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The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

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King's College London for the degree of Doctor of
Philosophy in Health Psychology**

Supervised by Dr Janet Anderson & Professor John Weinman

Abstract¹

The ultimate aim of this six study research programme was to develop and evaluate an intervention to promote medication adherence for osteoporosis patients. Mixed methods were used, with a combination of qualitative, quantitative and interventional approaches. Each study involved the investigation of the psychological factors which contributed to adherence to osteoporosis medication. In addition to data collection through interviews and questionnaires, participants were asked to draw how they visualized their osteoporosis.

This research drew on Leventhal's Self-Regulation Model (Leventhal et al, 1984) and Witte's Extended Parallel Process Model (Witte, 1992). The first three studies explored the role of psychological factors in osteoporosis medication adherence. The following factors were found to be related to adherence: concerns about medication (studies 1 and 3), motivation (study 3) and self-efficacy (study 3). Further, study 2 suggested that misconceptions about osteoporosis may also contribute to treatment non-adherence. Study 4 tested the psychological impact of the intervention materials. The drawing element of the research indicated that drawing the condition enabled patients to express their emotional response it (study 2).

Findings from the first four studies led to the design of a theory-based psychological intervention. The intervention comprised: psycho-education, motivational interviewing and plan-setting and was tailored to the needs of each individual. Medication adherence increased for seven of the eight study participants. Post-intervention, patients reported increased understanding of osteoporosis, a greater perceived need for medication and a stronger belief that osteoporosis medication could reduce the risk of osteoporotic fractures. Further, the evaluation suggested that the tailored element of the intervention was largely responsible for the increases in adherence (study 6).

The key findings were that i) osteoporosis patients have misconceptions about their bone health and their medication ii) psychological factors are related to osteoporosis medication adherence iii) creating a drawing of osteoporosis may elicit an emotional response to the condition and iv) a psychological intervention has the potential to increase adherence to osteoporosis medication. Further research with a larger sample is required to assess the intervention's effectiveness.

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Abbreviations

AIDS – Acquired Immune Deficiency Syndrome

BMA - British Medical Association

BMD - Bone Mineral Density

BMQ – Beliefs about Medication Questionnaire

BPS – British Psychological Society

CSM – Common Sense Model

DEXA – Dual Energy X-ray Absorptiometry

DHP – Division of Health Psychology

DNA – Did Not Attend

DoH- Department of Health

DOTMQ – Difficulties Of Taking Osteoporosis Medication Questionnaire

EPPM - Extended Parallel Process Model

HBM – Health Belief Model

HIV – Human Immunodeficiency Virus

HRT – Hormone Replacement Therapy

IBM SPSS – International Business Machines Statistical Packages for the Social Sciences

IPQ – Illness Perceptions Questionnaire

HCP – Health Care Professional

HRT – Hormone Replacement Therapy

MHRA – Medicines and Healthcare Products Regulation Agency

MI – Motivational Interviewing

MPR – Mean Possession Ratio or Medication Possession Ratio

MRI – Magnetic Resonance Imaging

MRC- Medical Research Council

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NOF – National Osteoporosis Foundation

NOS – National Osteoporosis Society

NICE – National Institute for Health and Clinical Excellence

NHS – National Health Service

NMC – Nursing and Midwifery Council

PMT – Protection Motivation Theory

PIS – Participant Information Sheet

PPI – Patient and Public Involvement

SCM – Social Cognition Models

SD-Standard Deviation

SRM – Self-regulation model

TPB – Theory of Planned Behaviour

WHO – World Health Organisation

Introduction

This thesis will provide a contribution to the body of knowledge of the reasons for low adherence to oral medication prescribed for osteoporosis. Osteoporosis is a condition of bone deterioration, which commonly affects older people, though it can also occur in younger people to a lesser extent. The number of people worldwide aged 65 and over is expected to increase by approximately 850,000 each month (Kinsella & Velkoff, 2001). Increasing life expectancy in many parts of the world means that osteoporosis and the fractures caused by osteoporosis will result in an increasing burden to the population worldwide. Considering the severity of hip fractures, it is of high importance that innovative methods are designed to help osteoporosis sufferers to manage their bone health and prevent these debilitating fractures.

The main objective of the present research was to design and evaluate a theory-based behaviour change intervention to promote osteoporosis medication adherence, for patients with problems with medication adherence. At the heart of the intervention lies the premise that psychological factors underpin behaviour, therefore attempts to change these psychological factors may have an impact on the behaviour. Given the theorised link between psychological factors and behaviour, it is expected that some psychological factors (e.g. beliefs and emotions) may act as barriers to adherence. A series of studies guided by the Medical Research Councils (MRC's) framework for the design and evaluation of complex interventions (Campbell et al, 2000) led to the design of an innovative adherence intervention.

Four intervention development studies (both qualitative and quantitative) were undertaken to inform the design of a pilot multi-faceted behaviour change intervention. The objective of these studies was to find out as much as possible about osteoporosis medication adherence before designing an intervention. An outline of the stages of adherence intervention development is provided below.

The opening chapter will provide a review of the clinical background and definition of osteoporosis, given that extensive knowledge of the medical condition under investigation is required for the delivery of a behaviour change intervention with this

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population of patients. Both the aetiology and the risk factors for osteoporosis will be discussed, as well as the relevant pharmacological and non-pharmacological treatments. In addition, the ways in which health psychologists can help to improve health outcomes for osteoporosis patients will be outlined.

Chapter two is a discussion of the problem of low adherence to medication, firstly as a general problem across medical conditions, progressing to focus specifically on this problem in relation to osteoporosis medication. The estimated prevalence of non-adherence will be documented, as well as the known reasons for low adherence.

The next chapter provides a discussion of the literature focussing on the potential solutions to the problem of low medication adherence. Behaviour change interventions previously carried out to improve adherence to osteoporosis medication are discussed. A key section of this chapter is a review of the relevant literature and theories which could be applied to the problem of low adherence to medication. Examples of previous applications of these theories to the problem of low medication adherence are included.

Chapter four provides a summary of the previously presented literature and progresses to explain a novel method which was used to design an intervention to improve adherence to osteoporosis medication. This chapter discusses the MRC's framework for the design and evaluation of complex interventions, which was used to guide the stages of intervention development. This chapter outlines the two health psychology theories that were selected to inform the design of the present research, with diagrams to show how the theories were operationalised. The two theories used were an extended self-regulation model (Leventhal et al, 1984; Horne, 1997) and the extended parallel process model (Witte, 1992).

The fifth chapter presents study 1; which is a critical review of the psychological determinants of adherence to osteoporosis medication. All previously published studies which aimed to quantify the relationship between psychological factors and adherence were included. The studies were assessed for quality before the data were synthesised in order to produce a list of the psychological factors related to non-

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adherence to osteoporosis medication. This enabled the identification of gaps in the literature, which brought a focus to the research presented in the remainder of the thesis.

The sixth chapter describes study 2, which is a qualitative study titled: 'how do osteoporosis patients perceive their condition and medication.' To gather information about how patients perceived their condition, they were interviewed and asked to draw how they visualised it. The interview schedule was based upon two theories of behaviour change, to explore whether these theories would be appropriate to underpin an adherence intervention for osteoporosis patients.

Chapter seven presents study 3, a cross-sectional questionnaire study drawing on two theoretical models to investigate the relationship between illness perceptions, emotional responses, risk perceptions, medication beliefs and adherence to osteoporosis medication. Patients' difficulties with taking osteoporosis medication were also assessed. The aims were to identify the psychological predictors of adherence and to evaluate the explanatory value of a range of potential predictors.

The eighth chapter describes study 4, which is a questionnaire study to assess how patients respond to some potential intervention materials. The study was set to explore how patients respond to visual images/pictures of osteoporosis and to investigate which images might be effective to use in an intervention to promote medication adherence. A review of the use of visual images to communicate about health in other clinical settings is included.

Based upon the results of the studies described above, an adherence intervention was designed and the research aim was to assess participants' response to the intervention. Chapter 9 presents the Adherence To Osteoporosis Medication (ATOM) intervention (study 5). A process evaluation of the ATOM intervention is presented in chapter 10 (study 6). The final chapter provides a general discussion, with the implications for the design of a future intervention to promote adherence to osteoporosis medication.

1 Osteoporosis; a clinical background

Chapter overview

Osteoporosis is a common chronic, asymptomatic skeletal disease which primarily affects older people. The prevalence of chronic illness is rising due to increasing life expectancy and our lives are becoming progressively more sedentary (in the developed world). It is predicted that by the year 2050, there will be over 250,000 people living in the UK over the age of 100, in comparison to 10,000 in 2008 (NMC, 2009). Moreover, in the UK 'by 2018 nearly three million (mainly older) people, will have three or more conditions all at once' (DoH 2012, p9). Hence it is vital that health researchers strive to find methods to facilitate patients' self-management of chronic conditions.

The opening section will provide the clinical background and definition of osteoporosis. The prevalence of osteoporosis will be described, as well as future predictions of worldwide case numbers. Potential causes and the consequences of this condition will be discussed. The second section will describe the risk factors for osteoporosis, under the broad headings of controllable and uncontrollable, which will highlight the illness self-management required from individuals with osteoporosis. The third section will discuss the treatment options available for osteoporosis patients. Finally, areas in which health psychologists may be able to help patients suffering with osteoporosis to improve their bone health will be identified.

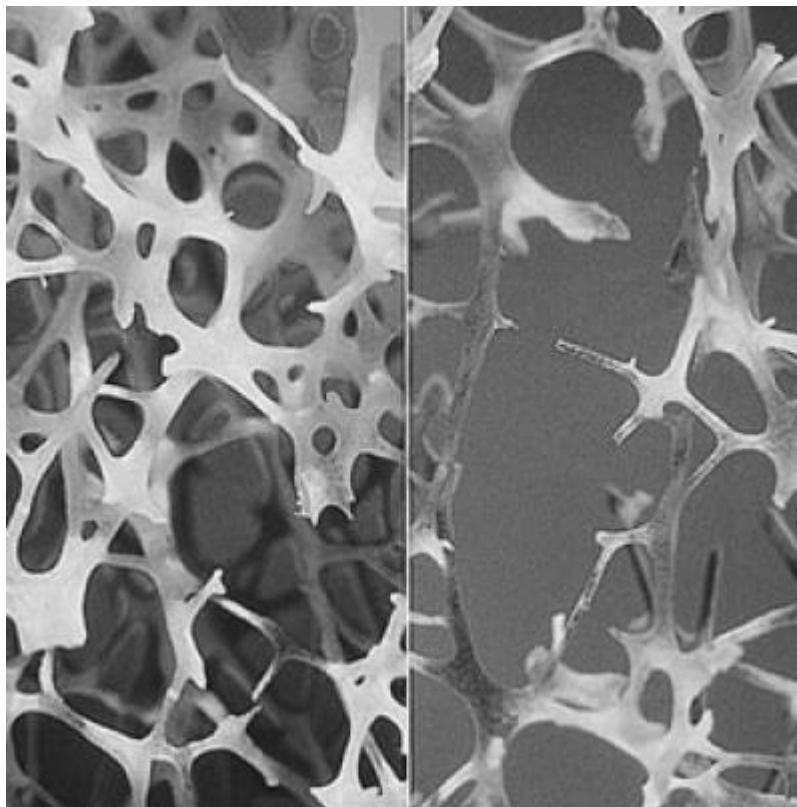
1.1 Osteoporosis clinical background

1.1.1 Definition

Osteoporosis is a condition of the skeletal system for which there is no known cure. It has been defined as 'a disease characterised by low bone mass and micro-architectural deterioration of bone tissue, leading to enhanced bone fragility and consequent increase in fracture risk' (WHO, 1994). In other words, bones affected by osteoporosis become thin and weak and break easily (Eastell, 2005). Hence it is a condition which puts a patient at high risk of suffering a fracture. While there is no cure for osteoporosis, the weakening of bones can be decelerated using medication and non-pharmacological treatments described later in this chapter.

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Osteoporosis has been called 'the silent thief of bone' because it is asymptomatic in the majority of cases (O'Connor, 1997). The definition of osteoporosis has developed and progressed, mirroring increasing medical knowledge of the features of the condition (Cummings et al, 2002). A French pathologist called Jean Georges Chretien Frederic Martin Lobstein 'the Younger' first discovered osteoporosis in 1820 and gave the disease its name (Schapira & Schapira, 1992). The term 'osteoporosis' is derived from the Greek words 'osteon' and 'poros' which when combined mean 'porous bone.'



Non-osteoporotic bone

Osteoporotic bone

Figure 1. Electron microscope images of normal and osteoporotic bones

A clinical definition of osteoporosis includes a description of the quality of the bone, which is given in terms of bone mineral density (BMD). BMD refers to the amount of minerals (such as calcium) in the bone and is now accepted as a key measure in determining a diagnosis of osteoporosis. In clinical practice, osteoporosis is diagnosed when the BMD in the lumbar spine, the femoral neck or the total hip is less than 2.5 standard deviations (sds) below the normal BMD for a healthy 30 year old (Kanis et al,

1994). Osteopaenia is the term used to describe a bone condition in which BMD is in the range between 1.5 and 2.5 sds below that of a normal healthy 30 year old and is a precursor to osteoporosis (Kanis et al, 1994). The clinical definition allows osteoporosis to be labelled as a disease rather than merely a risk factor for fracture (Schapira & Schapira, 1992). BMD measurements form part of the basis for decisions about treatment options, along with other risk factors described below.

The progression towards a clinical definition reflects advancement in both knowledge and medical technology, which now allows BMD to be measured and quantified using a Dual Energy X-ray Absorptiometry (DEXA) scan. However, the problem with such clinical definitions is the implication that there is a 'normal' bone mass to which everyone can be compared. It is argued that it would be more worthwhile to make a comparison of an individual's peak BMD i.e. the point at which bones are strongest across the life span (usually between the ages of 20 and 30), with their BMD in later life (Fogelman, 1989). BMD measurements could then be used to monitor bone deterioration by comparison with peak bone mass.

Bone is a living bodily tissue. From birth until death, bone is continuously being built up (formation), by osteoblast cells and broken down (resorption), by osteoclast cells through a process called bone turnover, also known as bone remodelling (Cummings et al, 2002). With increasing age comes an increase in the rate at which bone is broken down. This means that in older age the process of bone turnover results in an overall net loss of bone. The functional problem in osteoporosis is related to the speed of bone turnover, in which osteoclasts break down the bone faster than osteoblasts can replace it. Recently, it has emerged that bone turnover can be monitored using chemical bone markers, though they cannot be used to diagnose osteoporosis (Biver, 2012).

1.1.2 Prevalence

Osteoporosis is a very common condition and although osteoporosis can affect men, most sufferers are women, usually post-menopause. In postmenopausal women, bone loss is exacerbated by a lack of oestrogen (Nordin et al, 1966). It is estimated that

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osteoporosis affects 50% of women and 30% of men over 65 years of age (Wolf et al, 2000). For women aged 80 years of age and over, the prevalence of osteoporosis is estimated at 70%; for women aged 60 and under, it is 15% (Melton et al, 2005). Osteoporosis afflicts people worldwide; it was estimated that 673 million people worldwide had osteoporosis in 2005 and if current trends in the ageing population of the world continue, this figure is predicted to at least double by 2050 (Reginster & Burlet, 2006). In the UK it is estimated that three million people suffer with osteoporosis (Burge et al, 2001). Its prevalence for people over 50 years of age is 50% for women and 20% for men (Van Staa et al, 2001).

The areas of the body most commonly affected by osteoporotic fractures are the wrist, hips and spine (Blouin et al, 2008). In the year 2000 it was estimated that the worldwide number of new osteoporotic fractures was nine million; 1.6 million of these were hip fractures; 1.7 million were forearm fractures and 1.4 million were vertebral fractures (Blouin et al, 2008). With increasing life expectancy, the number of people living with one or more chronic conditions is rapidly growing (Stephens & Flick, 2010). This means that patients live for longer with a potentially reduced quality of life and increased reliance on the healthcare system. If healthcare services do not improve the way in which osteoporosis is managed and prevented, these figures will continue to rise dramatically.

1.1.3 Diagnosis and monitoring

The asymptomatic nature of osteoporosis in its early stages means there are no bodily indications of a problem and no discernible symptoms. Therefore it is very difficult to diagnose the disease until a fracture occurs (Kanis et al, 2004). This means that people are often unaware of having osteoporosis and do not realise how easily they can break a bone. This can result in people having pain from undiagnosed fractures for long periods of time. Although DEXA scans (discussed above) can detect osteoporosis and osteopaenia, it is common for a patient to first learn of the condition when they suffer from one or more fractures.

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The order of events is usually that a fracture signals to healthcare professionals that the patient may have low bone mass; hence a fracture is suffered before a diagnosis of osteoporosis is given in the majority of cases. This is unfortunate because if a patient could be made aware of their poor bone health early on, they could take action to prevent the situation from deteriorating to the point where they suffer a fracture. A patient will be diagnosed with osteoporosis based upon how the fracture was sustained and by taking a host of other factors into account (which will be discussed below in the risk factors section). It is not routine practice within the NHS for older people to be screened for osteoporosis. The national osteoporosis society argues that routine screening/scanning would be of great benefit to patients (Nelson et al, 2002), as this would enable patients who are a high risk of fracture to take preventative steps. However, evidence for doing so is difficult to obtain, particularly in light of the debate as to whether BMD predicts fracture risk (discussed below).

There is a debate as to whether BMD should be used to assess fracture risk. The use of BMD as a measure of osteoporosis and an indicator for medical intervention is contested by many researchers (see for example McGrother et al, 1999; Ruhl, 2008; Napoli, 2009). These authors believe that bone mineral density cannot predict fracture risk, because there are a host of other factors to take into account (these factors are described in the following section). On the contrary, others believe BMD should be used to predict fracture risk because 'the relationship between bone mineral density and fractures is analogous to that between blood pressure and stroke and it is just as strong' (Eastell, 1999).

It is now common in clinical practice for BMD and other risk factors to be taken into account before deciding whether osteoporosis/osteopaenia requires treatment using the FRAX[®] tool. FRAX[®] is a web based tool which has been developed by the World Health Organisation (WHO). It calculates an individual's risk for suffering a fracture (with or without a bone mineral density reading) and results in a score which is said to be able to determine a patient's 10 year fracture risk (Kanis et al, 2008). FRAX[®] uses the following risk factors to determine fracture risk: age, gender, weight, height,

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current smoking, BMD, prior fracture history, parental history of hip fracture, smoking status, alcohol consumption, rheumatoid arthritis and steroid use.

Markers of bone turnover can be used to investigate and measure the process of bone remodelling. Markers include the cells involved in the formation and resorption of bone, osteoblasts and osteoclasts. Resorption markers can be measured in urine and serum, whereas formation markers can be measured in serum or plasma (Cummings et al, 2002). Biochemical markers can also be used as a factor to determine a FRAX[®]™ score. Biochemical markers are helpful in the assessment and monitoring of an individual with osteoporosis for two reasons: a) they can highlight underlying causes of bone loss, providing the basis for a more detailed evaluation of the patient and b) they can also be used to assess response to treatment (providing a baseline measurement has been taken before medication is begun). However, some changes found can be due to natural variability in the markers (Nishizawa et al, 2004).

1.1.4 Consequences of the condition

Osteoporosis can cause sufferers to experience painful fractures, hospitalisation and serious long term health consequences such as physical disability, reduced quality of life, loss of independence, decreased confidence and even mortality (Pasco et al, 2005). Due to bone weakness, the major complication for people who have osteoporosis is an increased risk of a fragility fracture (also known as insufficiency fractures). A fragility fracture is a broken bone sustained on low impact (Giangregorio et al, 2009) e.g. by coughing, bending over or sneezing. Fractures are usually classified as vertebral (spinal) and non-vertebral and can vary greatly in terms of severity and recovery depending upon their bodily location. Osteoporosis patients often suffer many fractures, some undiagnosed for a long period of time. Fractures can lead to chronic pain. Patients' fracture risk is manageable / preventable by patient adherence to treatment recommendations which will be discussed below.

Hip fracture

Hip fractures are the most debilitating type of osteoporosis related fracture, which in the vast majority of cases require hospital admission. As well as being associated with

a poor quality of life, hip fractures are associated with mortality. Once a patient suffers a hip fracture, they can become immobile for a long period of time and around one third of these patients does not recover (Cooper, 1997) and can require long-term medical care. Recently, a systematic review was conducted to explore hip fracture related mortality. It was found that hip fracture patients had between 8.4% and 34% increased relative risk of mortality when compared to age matched controls in the first year after hip fracture (Abrahamsen et al, 2009). The death rate within one year of a neck of femur (hip) fracture is typically reported as between 20% and 35% (Boereboom et al, 1991). The fact that fractures are related to mortality further highlights the importance of fracture prevention.

Forearm Fracture

Fractures of the distal forearm are usually caused by a fall on the outstretched hand, commonly among the middle aged and elderly (WHO, 1994). A fracture of the forearm can result in the need for surgical procedures and dependence on others to carry out daily activities (WHO, 2003). While fractures of the forearm do not cause as many problems as hip fractures, they can increase the risk of future fractures (Silman, 1995).

Vertebral Fracture

Many vertebral fractures are asymptomatic and remain undetected (Cooper et al, 1992). One of the most dreaded consequences for osteoporosis patients (both aesthetically and as an increased risk factor for pneumonia) is kyphosis, which involves curvature of the upper spine (an anterior curvature). Kyphosis is also known as a hunchback or dowagers hump. This can result from fractures in the upper spine and can cause impaired mobility, discomfort, breathing difficulties, loss of appetite and loss of height (Black et al, 1994; Katzman et al, 2011). Kyphosis and loss of height are the only visible signs of osteoporosis.

1.2 Risk Factors

While the causes of osteoporosis are not yet fully understood, the risk factors are known and can be split into two categories; controllable and uncontrollable. The uncontrollable risk factors include: age, gender, heredity, race, hyperparathyroidism,

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vertebral deformity, renal failure and amenorrhoea. As age increases the risk of osteoporosis also increases. The controllable life-style risk factors for osteoporosis are: diet, exercise (both lack of exercise or over exercise), falls, smoking, anorexia, alcoholism and osteoporosis medication adherence.

Osteoporosis can be either a primary condition or secondary to another medical condition. When it is a primary condition in women, it is known as postmenopausal osteoporosis, due to the loss of oestrogen that takes place during the menopause. Oestrogen is known to protect against bone loss (Nordin et al, 1966). There are many diseases to which osteoporosis is secondary, for example: Cushing's disease, kidney disease and metastatic cancer (Gallagher, 1990). There are iatrogenic causes of osteoporosis secondary to drug use, such as glucocorticoids (Cummings et al, 2002) and Arimidex, which is a drug used to treat breast cancer. Further, co-morbidities which increase a person's risk of falling may make them at increased risk of fracture, e.g. glaucoma (resulting in impaired vision) and alcoholism (resulting in ataxia). Diseases or medical conditions such as: rheumatoid arthritis, stroke, transient ischemic attack, muscular atrophy, motor neurone disease and Parkinson's disease can cause people to become immobile can also result in osteoporosis (Cummings et al, 2002). In addition: anorexia, coeliac disease and food intolerances which cause malnutrition can also result in osteoporosis.

As previously mentioned, osteoporosis is predominantly a female disease. There are three main reasons for this: 1) Oestrogen is protective against osteoporosis so when women produce less oestrogen post-menopause, they have an increased risk of developing the condition (Nordin et al, 1966). 2) As a general rule, women have a lower peak bones mass than men. In other words, women usually have a thinner body build and smaller bones. 3) Women of some cultures/religious beliefs are required to cover up some or all of their bodies, which can prevent them from absorbing vitamin D, which is obtained through sunlight. The role of vitamin D in bone health is explained in more detail below.

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Other risk factors (which are difficult to determine as controllable or uncontrollable) include: steroid use, malabsorption (gut disorders), thyrotoxicosis, myeloma, primary biliary cirrhosis, hypogonadism, previous fragility fracture and mastocytosis (Harper & Webber, 1998; Cummings et al, 2002). More recently it has been found that major depression is a risk factor for low bone mineral density (Yirmiya & Bab, 2009) and a small relationship has been found to exist between stress and bone mineral density (Yilmaz & Eren, 2009).

A balanced diet is important for healthy, strong bones. While it is well known that calcium is an essential dietary component for healthy bones, the benefits of magnesium and potassium are less well documented. A four year longitudinal study carried out by Tucker et al (1999) with a large sample of osteoporotic men and women found that higher intake levels of potassium, magnesium and fruit and vegetables were associated with greater bone mineral density scores (in both the hips and forearm). The evidence for a relationship between obesity and osteoporosis is conflicting. Whereas weight and load on the bones might be beneficial for bone health, childhood obesity has also recently been linked to a reduction in bone mineral density in later life (Slavkin, 2000).

Research that has focused on education status and its possible links to osteoporosis has yielded mixed results. It would be reasonable to suggest that individuals who have higher levels of education would be better informed about health protective behaviours and therefore less likely to suffer from osteoporosis. However, one group of authors found the opposite to be true (Brennan et al, 2009). An explanation for this finding could be that people with higher levels of education are thinner (due to being well informed about the health risks of being overweight) and being thin leads to smaller bones which increases the chance of osteoporosis (Clark & Tobias, 2010). This is important because it shows that while socio economic status may influence bone health, the mechanisms behind how this occurs remain unclear. Previous research has shown that marital status was associated with fractures (Brennan et al, 2009). Those who are married or living with a partner were less likely to suffer a fracture than those living alone. This is likely to be due to increased social support.

1.3 Treatment for Osteoporosis

While there is no cure for osteoporosis, there are various treatments which can improve bone mineral density and therefore reduce the risk of fracture. Osteoporosis is of interest to health psychologists as it is a chronic condition in which successful treatment requires self-management. Self-management is defined as ‘the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition’ (Barlow et al, 2002). Successful management of osteoporosis involves: medication-taking (when it is prescribed), a calcium-rich diet (or supplementation), vitamin D from sunlight (and from the diet to a lesser extent), weight-bearing exercise and following treatment recommendations. Chronic illness sufferers are not necessarily proficient at self-managing their illness, therefore, there is scope for health psychologists to have a beneficial impact on improving the self-management of chronic conditions such as osteoporosis.

Treatment for osteoporosis requires taking action in order to reduce the risk of an adverse health event in the future. The treatment options for osteoporosis can be separated into two categories; pharmacological and non-pharmacological. Both types of treatment require elements of self-management on the patient’s behalf to ensure that they follow their treatment regimes. Poor adherence to treatment is a major clinical problem which prevents treatments from being successful; this problem is the focus of the present research (discussed in chapter 2). The pharmacological and non-pharmacological treatment regimes for osteoporosis patients are detailed below.

1.3.1 Pharmacological Treatments

There are a wide range of pharmaceuticals available for the treatment of osteoporosis. These treatments include two distinct types: antiresorptive and anabolic. Antiresorptive treatments such as bisphosphonates and denosumab inhibit osteoclast activity (or the breakdown of bone). Anabolic treatments such as strontium ranelate and parathyroid hormone can build new bone. Hormone Replacement Therapy (HRT) and calcium and vitamin D supplementation are also used in the treatment of osteoporosis. These will all be discussed in this section. Other treatments aside from

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medication include surgical options, such as titanium plates, pins or vertebral plasty, which can help to support the spine and prevent fractures.

Table 1. Change in Spinal BMD and Fracture Risk in Major* Trials of Osteoporosis Therapy for Postmenopausal Osteoporosis (Cefalu, 2004)

Medscape® www.medscape.com		Baseline		Outcomes		
Study (duration)	Drug and dosage	Vertebral fracture (% patients)	Spine T-score	Spine BMD† increase	Fracture risk reduction	
					Vertebral‡	Nonvertebral
VERT-NA (3 years) ¹¹	Risedronate 5 mg/day	= 80	-2.4	4.3%	41% (<i>P</i> = 0.003)	39% (<i>P</i> = 0.02)
VERT-MN (3 years) ¹²	Risedronate 5 mg/day	100	-2.8	5.9%	49% (<i>P</i> < 0.001)	33% (<i>P</i> = 0.06)
FIT-prevalent (3 years) ¹⁷	Alendronate 5 mg/day × 2 years then 10 mg/day × 1 years	100	≤ -2.1	6.2%	47% (<i>P</i> < 0.001)	12% (<i>P</i> = 0.13)
FIT-absent (4 years) ¹⁶	Alendronate 5 mg/day × 2 years then 10 mg/day × 2 years	0	≤ -2.1	6.8%	44% (<i>P</i> = 0.002)	20% (<i>P</i> = 0.06)
MORE (3 years) ¹³	Raloxifene 60 mg/day	= 10#	≤ -2.5	=2.6%	50% (<i>P</i> < 0.05)	10% (<i>P</i> = 0.24)§
		= 90¶	≤ -2.5	=2.6%	30% (<i>P</i> < 0.05)	
PROOF (5 years) ¹⁴	Salmon calcitonin nasal spray 200 IU/day	78	≤ -2.0	0.6%	33% (<i>P</i> = 0.03)	12% (<i>P</i> = NS)
Teriparatide (21 months) ²⁹	Teriparatide 20 µg/day	100	-2.6	8.6%	65% (<i>P</i> ≤ 0.001)	35% (<i>P</i> = 0.04)

BMD = bone mineral density; FIT = Fracture Intervention Trial (prevalent [prevalent vertebral fracture], absent [absent vertebral fracture]); MORE = Multiple Outcomes of Raloxifene Evaluation; NS = not significant; PROOF = Prevent Recurrence of Osteoporotic Fractures; VERT-MN and VERT-NA = Vertebral Efficacy With Risedronate Therapy-Multinational and -North American trials, respectively; WHI=Women's Health Initiative

*Defined as double-blind, randomized, and placebo-controlled and having enrollment of > 1000 patients

†Treatment minus placebo

‡Vertebral fractures determined by morphometry

§Pooled results for all 5129 women treated with raloxifene 60 or 120 mg/day, regardless of baseline vertebral fracture status

#Subgroup of patients without prevalent fractures

¶Subgroup of patients with ≥ 1 fracture

Source: Curr Med Res Opin © 2004 Libropharm Limited

Source: Curr Med Res Opin © 2004 Libropharm Limited

There is strong evidence from many studies that osteoporosis can be effectively managed and osteoporotic fractures can be prevented with medication (Cranney et al, 2002; Cefalu, 2004; Wells et al, 2008). However, the medication effectiveness relies on it being taken regularly in the fashion prescribed, which will be discussed in chapter 2. The following will discuss the most commonly used agents for treating osteoporosis.

The treatments described in this section have all been found to significantly reduce the risk of fracture. Bisphosphonates are the first line treatment choice for osteoporosis (DeVilier, 2009). They work by slowing down the process of bone resorption, (i.e. reducing the speed of bone loss) and have been shown to reduce fracture risk and increased bone strength (Cranney et al, 2002; Wells et al, 2008). The majority of patients will respond well to the medication, provided the treatment is taken correctly and regularly. There are many different types of bisphosphonates available, with various dosing frequencies and methods of administration. Bisphosphonates can be taken in tablet form (for daily and weekly doses) and intravenously (once every three months and yearly doses). Daily bisphosphonates called alendronate (Fosamax) were previously the most common choice of treatment for osteoporosis. Scientific advancement has meant that lower dosing frequencies, such as the weekly

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(alendronate or risedronate) and monthly (ibandronate) have been developed and are now more commonly prescribed than daily doses. There is also a three monthly infusion called pamidronate. Oral bisphosphonates are recommended for use for up to five years (Black et al, 2006). More recently an annual infusion called zoledronate has been approved for the treatment of postmenopausal osteoporosis (Black et al, 2007).

When patients are prescribed any of the orally administered bisphosphonates, they are required to take them on an empty stomach, because food interferes with the absorption of these drugs. Patients are also required to take the medication with a large glass of plain water and to remain upright (sitting or standing, not lying) for half an hour after ingesting it. The instruction to remain upright is required to prevent severe side effects. One of the problems with daily/weekly oral bisphosphonates is that they are known to produce unpleasant side effects e.g. indigestion, reflux, diarrhoea, joint pain for some patients. In rare cases bisphosphonates have been linked to osteonecrosis of the jaw (DeVilliers, 2009). Bisphosphonates have also been linked to oesophageal erosion and oesophageal cancer (Green et al, 2010). Before patients are prescribed bisphosphonates, they should be advised to have a dental check-up. This is because a tooth extraction in a patient taking bisphosphonates could lead to serious complications such as osteonecrosis of the jaw (Marx 2003).

The introduction of a yearly infusion of zoledronate as the routine treatment for osteoporosis patients within the NHS has eliminated several of the problems associated with non-adherence to medication. This is because patients do not have to remember to take their medication regularly and also, there are no oesophageal side effects. Intravenous doses require the patient to make a short hospital visit, as the infusion is administered over at least fifteen minutes. Although zoledronate demonstrates perhaps the best overall efficacy data thus far for any osteoporosis treatment (Rizzoli, 2010), it is currently not available to all NHS patients, as it is awaiting clearance from the National Institute for Health and Clinical Excellence (NICE). In addition, some patients suffer acute flu like symptoms after the first infusion in particular and the drug is used with caution in those with renal impairment.

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Strontium ranelate (Protelos) is an anabolic agent which is commonly prescribed for osteoporosis and has been found to reduce the risk of fracture (Stevenson et al, 2007). Strontium ranelate is a powder which is dissolved in water and is taken orally. The administration directions are not easy; patients are required to take the medication midway through a four hour fast. In other words they are required to take it two hours after eating and then fast for two further hours. The reason for fasting is that the medication is poorly absorbed. Patients are advised to take it two hours after dinner before they go to bed. There can be side effects with this medication which include: diarrhoea, nausea, loss of memory and rash. While strontium ranelate has been found to improve Quality Adjusted Life Years (QALYs), it was found that strontium ranelate is not as cost effective as bisphosphonates (Stevenson et al, 2007). It is therefore often given to patients who cannot tolerate the side effects of bisphosphonates.

Another anabolic agent used to treat osteoporosis is teriparatide (Forsteo), which is a parathyroid hormone. Researchers have found this medication to be very effective in improving bone mineral density and it has been named the gold standard for treating osteoporosis (Neer et al, 2001). It can be either self-administered by daily injections, or administered by a team of nurses who visit patients at home every day. However, it does not improve bone density for all osteoporosis sufferers. It is a very expensive medication and is currently only recommended for patients over 65, or those with very severe osteoporosis who have suffered multiple fractures.

HRT is considered as a second line treatment option for osteoporosis in older postmenopausal women. It produces effects similar to bisphosphonates (Cefalu, 2004). HRT has a role in the treatment of younger women at high risk of fracture, particularly if they have menopausal symptoms. However the British Medical Association (BMA) warns that HRT increases the risk of breast cancer (Mayor, 2003) and stroke.

1.3.2 Non-pharmacological treatments

There are also non-pharmacological treatments which can be used to prevent fractures. These involve diet, exercise, falls prevention and adherence, which are the major modifiable behaviours which can impact osteoporosis (aside from medication-

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use). Health psychologists can design behaviour change interventions for patients to promote engagement in these health related behaviours. Many of the health behaviours discussed below are also relevant to the self-management of other medical conditions.

A balanced diet is needed to maintain the structure and function of the skeletal system. Various vitamins and minerals within the diet are important for maintaining bone health. Calcium is needed to keep bones and teeth rigid and is important for many of the body's metabolic processes (Cummings et al, 2002). It is believed that calcium needs to be built up from when a person is young and into early adulthood (around 25-30), in which peak bone mass is reached. Calcium can be obtained from the diet from milk and other dairy products as well as through supplementation. Much of the calcium consumed by an individual is not absorbed by the body. Post-menopause, women excrete more calcium due to a decrease in the ability to absorb calcium. As for many other medical conditions, high sodium chloride (common salt) intake is not advised for patients with osteoporosis. This is because sodium competes with calcium for absorption into the kidneys (Saric et al, 2005) and it can cause more calcium to be excreted in urine (Caudarella et al, 2009). Malnutrition such as anorexia nervosa may have a detrimental effect on bone health because it results in a failure to reach peak bone mass which is a result of a lack of vitamins and minerals (Seeman et al, 1992).

Vitamin D is a hormone which is essential for healthy bones; it is absorbed into the body through exposure to sunlight (Holick, 2007). Vitamin D is integrally involved in bone metabolism through stimulation of calcium absorption from the intestine and resorption from the kidneys. Deficiency in vitamin D is common due to the weather conditions in countries such as the UK, where it is difficult for individuals to get the required level of sunlight exposure throughout the year. To a lesser extent vitamin D can be obtained from food such as oily fish. Vitamin D deficiency is known as osteomalacia and can result in osteoporosis, muscle weakness and reduced immune system function. However, there is mixed evidence as to whether vitamin D supplementation can reduce the risk of fracture (Sahota, 2010).

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People who are physically active have higher bone mass; this is important when considered in conjunction with the increase in sedentary lifestyles typical of contemporary society. This sedentary lifestyle could be detrimental to bone health. To reduce the likelihood of fractures, it is important for people to engage in weight bearing exercises such as walking - which can strengthen the bone (Inoue, 1993). There is a curvilinear relationship between weight bearing exercise and bone mass. Increasing the weight loaded onto bones increases bone mass up to a certain point, whilst not enough weight bearing exercise can be detrimental to bone health. Extensive exercise (e.g. marathons) can also be detrimental to bone health as too much pressure can be placed on the skeleton (Torstveit, 2010). While weight bearing exercise is recommended for osteoporosis patients, this should be carried out with caution, due to an increased risk of falling.

Falling over is a common cause of fracture for older people. Patients with osteoporosis need to do whatever they can to prevent themselves from falling over, due to their high fracture risk even with low impact falls/injury. Falls prevention can involve: removing hazards from the environment, muscle strengthening and balance training exercises (Yardley et al, 2006). Once a person has suffered a fracture they are at increased risk for subsequent fractures (Gardsell, 1989). For example, a prior vertebral fracture significantly increases the risk of a subsequent vertebral fracture (Lindsay et al, 2001). Therefore falls prevention is a high priority in reducing the consequences of osteoporosis. In conjunction with other methods of falls prevention, individuals can wear hip protectors to protect themselves against hip fracture (Handoll, 2010). They can also be made aware of the importance of always holding on to a rail when they climb stairs.

While moderate amounts of alcohol may be beneficial to bone health, excessive intake can result in an increased risk of falling. As well as making people ataxic and hence more likely to fall, a high intake of alcohol results in reduced bone formation. However, moderate alcohol intake has not been linked to an increased fracture risk and recently it has been indicated that barley which is found in beer could be

beneficial to bone health, because barley contains silicon which improves bone mineral density (Casey & Bamforth, 2010).

1.4 Summary

Osteoporosis is a very common condition (particularly in women) and the fractures caused by osteoporosis can result in severe disability and even mortality. There is a wide range of effective treatments available to lower the risk of fracture. Osteoporosis is a condition which requires self-management from the patients, due to the chronic nature of this condition. There is scope for health psychologists to develop self-management interventions with an aim to improve bone health and prevent fractures. This can be achieved through the promotion of behaviour to reduce the risk of fracture such as: medication-taking, maintaining a diet rich in calcium, exposure to sunlight for vitamin D, weight bearing exercise and falls prevention. Adherence to the recommended health related behaviour is a key focus for health psychologists. The next chapter will discuss the problem of low adherence to medication for the treatment of chronic conditions, a worldwide clinical problem which can lead to poor health outcomes for patients.

2 Adherence to medication

Chapter overview

This chapter will introduce the problem of non-adherence to prescribed medication, in two main sections. The first will describe the problem of low adherence to medication across medical conditions, including the prevalence, determinants and implications of non-adherence. The terminology used to describe patients' medication-taking behaviour will be described, namely compliance, adherence and persistence. In the second section, the same format will be used to discuss the adherence problem in relation to osteoporosis treatment.

2.1 Background

Health psychologists are interested in adherence to medication because of the behavioural influence it has on patients' health outcomes. It is well established that non-adherence to osteoporosis medication is associated with an increased risk of fracture (Siris et al, 2006; Patrick et al, 2010; Ross et al, 2011). Low adherence to treatment is a major public health concern worldwide, particularly for chronic conditions, which can require the burden of a lifetime of medication. Osteoporosis is a condition with serious personal costs for patients, including: painful fractures, hospitalisation, reduced quality of life and disability, as well as financial consequences for healthcare services. The medical profession prescribes medication which has been shown to be effective to lower the risk of fracture. However, success of the treatment depends on patient adherence (Cranney et al, 2002; Wells et al, 2008). Low levels of treatment adherence can result in increased hospital admissions which are preventable and are a waste of health care resources. Across medical conditions, patients who take their prescribed medication have been found to have better health outcomes. Yet osteoporosis has two clinical features that mean designing interventions for adherence are challenging; it is chronic and asymptomatic.

As well as being a potential cause of deterioration in a patient's health, it is estimated that with low adherence to treatment, the outlay to the NHS is up to £150m per year in medication costs (McDowell and Barnett, 2012). It has become essential to find

ways to help patients manage long-term conditions and improve their quality of life (DoH, 2012). Given that medication is the most common medical intervention (Horne et al, 2005), it is worthwhile investigating various ways of optimising treatment delivery, to prevent adverse health outcomes, enhance patients' quality of life and improve the quality of the healthcare service (Osterberg & Blasche, 2005; McDowell & Barnett, 2012). The NICE (2009) state that non-adherence to medication highlights a failure in health service delivery. Before designing behaviour change interventions to promote treatment adherence, it is vital to review the literature in order to select a behaviour change technique which is likely to be efficacious.

It is now commonly accepted that psychological and social factors play an important role in a person's illness experience, health choices and outcomes (Weinman & Petrie, 1997). For this reason, health psychologists are interested in the relationship between beliefs and health related behaviour. It is theorised that a patient's beliefs about their health and illness are important determinants of their illness self-management behaviour, such as medication-taking. Theories of this nature will be discussed in chapter three.

2.2 Terminology

The terminology used to describe patients' medication-taking behaviour has changed over time (Cramer et al, 2008). In the research literature, the term *compliance* was previously used to signify the extent to which a patient follows treatment regimens prescribed by their doctor (Miller et al, 1997). Recently, as the healthcare system has aimed to shift from 'doctor-centred care' to 'patient-centred care', the terminology used has also shifted to reflect this change (Endelman, 2000). For this reason, researchers now more commonly use the term *adherence* in place of *compliance*. The rationale for this terminology shift was to move away from the idea of patients passively following their doctor's orders, towards a doctor-patient agreement of treatment plans. Furthermore, the term *adherence* is intended to be less judgemental than *compliance* (McDonald et al, 2002) and would therefore facilitate a more collaborative doctor-patient relationship.

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More recently, Haynes et al (2008) suggested that adherence consists of two elements of medication-taking, *compliance* and *persistence*. Compliance and persistence have been defined as “the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen” and “the extent to which a patient continues to follow the treatment advice without a break and without stopping” respectively (Cramer et al, 2008 p 46). For the purposes of this thesis, the term adherence will be used to signify medication-taking behaviour, because the term *adherence* incorporates all elements of patients’ medication-taking behaviour.

There are various definitions of adherence; adherence has been defined as ‘the extent to which a patient’s behaviour...coincides with medical or health advice’ (p2868) (McDonald et al, 2002). NICE (2009) report that the term adherence ‘presumes an agreement between a doctor and patient’ (p3). DiMatteo et al (2002) describes non-adherence as a missed chance for therapeutic benefit. The terms *adherence*, *persistence* and *compliance* are often used interchangeably even though they refer to different elements of medication-taking behaviour, which can cause problems with analysing and interpreting adherence to medication data. Without a universal language to describe medication-taking behaviour, it is likely that researchers will measure different elements of it. For example, in studies of persistence, the duration over which doses are taken is measured.

2.3 The prevalence of non-adherence to medication

Patients with chronic, long-term conditions such as osteoporosis are noted to have problems with medication regimens, with an estimated 30-50% of medications (across countries and medical conditions) failing to be taken as prescribed (World Health Organisation, 2003). This has implications for patients, the healthcare system and society (NICE 2009). If a medicine is correctly prescribed, improving adherence (across medical conditions) would have greater health benefits than improving the nature of the medication (Horne et al, 2005). Interventions designed to improve adherence should focus on conditions which now have efficacious medications to treat them

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(Horne et al, 2005), however, medication-taking is a complex behaviour with no single factor predicting it.

Despite the large and growing body of research indicating the effectiveness of medication for many medical conditions (and the poor health outcomes associated with non-adherence), healthcare professionals still have great difficulty in convincing patients to follow medication and treatment advice in all specialities of the health care setting (NICE, 2009). In the research literature, it is estimated that only 50% of prescribed medications are taken (Haynes, 1996). It is expected that in practice, the rate of adherence is lower than that detected in research studies, given that research includes an element of adherence monitoring (Papaioannou et al, 2007).

When a doctor prescribes medication to an out-patient, self-management is required on the part of the patient to go and pick up their prescription and then to take the medication as directed. The problem of non-adherence is described as a hidden problem, difficult to detect by healthcare providers and concealed by patients (Horne et al, 2005). While non-adherence is often hidden, it has been stated that non-adherence usually manifests three months after a medication is prescribed (Cummings et al, 2002). Therefore interventions to target adherence and improve self-management are likely to be beneficial within the first three months of treatment.

2.4 Measurement

Obtaining a valid and reliable measurement of adherence to medication is a significant problem for researchers and to date there is no commonly accepted accurate measurement. There are a wide range of measures in adherence research, each with its own merits and flaws. Measures of adherence can be categorised as direct or indirect (Osterberg & Blaschke, 2005). Direct measures include direct observation and measurement of biomarkers in blood and urine. Indirect measures include self-reports (questionnaires, interviews or diaries), clinical outcomes, pill counters and performing pill counts, medication possession ratio (the number of doses collected from the pharmacy) and healthcare providers' opinion (estimation).

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In-direct measures of adherence are most commonly adopted by researchers due to their practicality. The use of self-reports is the most convenient and commonly used method of measurement in psychology research, yet its validity is questionable (Baumeister, 2007). Presentational bias is a major problem with self-report scales, because it may mean that people are motivated to present themselves as adherent rather than accurately reporting their medication-taking behaviour. The medication adherence report scale (MARS) is a commonly used (validated) measure of adherence to medication (Cohen et al, 2009). The MARS attempts to overcome problems of the accuracy of self-report data by starting with the following statement:

“Many people find a way of using their medicines which suits them.

This may differ from the instructions on the label or from what their doctor has said.

We would like to ask you a few questions about how you use your medicines.”

However, a further problem in using self-report is not only about relying on a patient to be truthful, but also to be accurate in their recall of events.

Pill counters are commonly used electronic devices which are fitted to a medication bottle and used to count the number of doses taken. Methods that involve taking an accurate measure of how much medication has been taken, such as pill counters, may influence adherence rates because patients know they are being monitored. Another way to monitor adherence to medication is to get a doctor's estimate of how much medication their patient has taken. The accuracy of this measure is limited (Brody, 1980). It is an opinion rather than a measure.

Another way to measure medication adherence is through the use of biomarkers. Biomarkers are chemicals found in blood or urine which indicate an individual's physiological state. While they may overcome the problem of errors in human judgement, they are not completely accurate as a measure of adherence because some patients may not be responding to the medication, even though they are taking it (Cummings et al, 2002). Further, they are not routine tests for osteoporosis patients.

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A measure to quantify adherence, which attempts to overcome many of the above mentioned biases, is to use electronic records of prescriptions that patients have collected from the pharmacy (although this is not feasible in the UK). This type of measurement is called the Mean Possession Ratio (MPR) (Andrade et al, 2006) which is estimated by the number of daily doses required, divided by 365; this provides the number of days of medication that is available to the patient during a one-year period. The problem with using the MPR is that it cannot accurately show a patient has actually used their medication - it only indicates that medication has been collected from the pharmacy. This poses a challenge for many reasons; aside from the problem of not knowing whether the patient has actually taken the medication, it will not then be accurate when a patient is required to change their medication. If a patient is asked to change their medication and they adhere to it, the MPR can make their adherence appear to be higher than 100% (Lekkerkerker et al, 2009). This measure could lead to an overestimation of adherence and over adherence is still classed as non-adherence. The data collected using MPR can be difficult to interpret.

Further, the MPR cannot measure whether the medication was taken as prescribed, on time, etc. For example, if the instructions state the medication should be taken in the morning, or should be taken on an empty stomach. The reasonable assumption in using this measure is that patients would not continue to collect medication that they were not using. A further problem is that data collected using the MPR relies on the data recorded by the pharmacy to be correctly entered. It is important to keep these issues in mind when reviewing studies which have used the MPR measure.

A previous suggestion to tackle the problem of selecting an adherence measure is to use two or more different measures together (Osterberg and Blaschke, 2005), but the usefulness of using various measures of adherence simultaneously is debateable. A recent study investigating adherence to Human Immunodeficiency Virus (HIV) medication found that using self- reports, MPR and biomarkers concurrently as measures of adherence made the results difficult to interpret, because each measure gave a different result which showed no relationship to the others (Holzemer et al, 2006). It is difficult to determine which of these measures of adherence are valid and

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reliable. Collecting adherence data in many different ways to look for comparisons was counterproductive in this study.

A further measurement issue to consider when designing adherence interventions is determining how long to measure medication-taking behaviour for i.e. the optimal amount of time to enable an accurate measurement of medication-taking, or the number of follow-up measurements required, e.g. 3 months or 6 months after beginning measurement (Haynes et al, 2008).

Health outcome data should always be collected as an outcome measure in interventions to improve adherence to medication (Haynes et al, 2008), e.g. the number of fractures sustained in the case of osteoporosis (Gleeson et al, 2009). When interventions do not measure the relevant health outcome(s), they are omitting an important indication of adherence, because health is the overall goal of adherence to medication. A systematic review investigating adherence to osteoporosis medication interventions excluded those studies which did not include the number of fractures as an outcome measure, because they were viewed as having missed the most important result (Imaz et al, 2010). One of the disadvantages of not measuring the relevant health outcomes is that it could lead to research which is less clinically relevant.

2.5 The determinants of non-adherence to medication

In order to understand non-adherence, Schousboe et al (2013) stated that 'understanding the aetiology of the phenomenon is critical to craft practical management strategies that may mitigate the problem' (p22). This means that before designing an adherence intervention, the determinants of non-adherence should be identified. The reasons for non-adherence to medication are multi-factorial; over 200 reasons have been documented by researchers (Vermeire et al, 2001) at the patient, health-care provider and system levels (Miller et al, 1997). It has been suggested that the reasons for non-adherence will vary from person to person (Solomon et al, 2010). There are many variables which may influence adherence to medication and the reasons for non-adherence are still poorly understood by health researchers and healthcare professionals. Studies indicate that demographic factors such as gender,

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race and socio-economic status are not consistently associated with adherence to medication (Horne et al, 2005).

Non-adherence to medication is often conceptualised by researchers as *intentional* and *unintentional* (Horne, 1997) and there is a large body of evidence to support this distinction (Wroe et al, 2002). This is a useful distinction, as it highlights the importance of understanding whether non-adherence is a conscious process or not. The reasons for non-adherence can also be classified as patient centred or doctor/organisation centred. This distinction is useful because recognition that the problem is also at the system level removes the blame from the patient (Barber, 2002).

Intentional non-adherence occurs when a patient makes an active deliberate choice to miss a dose of their medication (Horne, 1997). For example, deciding not to take medication to avoid unpleasant side effects would be classified as intentional non-adherence. Another intentional reason for non-adherence is related to not being able to feel the benefit of medication e.g. not perceiving that the drugs are working, or not perceiving a need for medication. Intentional non-adherence highlights the fact that patients' beliefs about their medication can play a big role in their decision about whether to take it, which will be discussed below.

Unintentional non-adherence is a more passive process. Some unintentional reasons for non-adherence include: lack of manual dexterity (and therefore inability to administer medication), problems with understanding how to administer the treatment and cognitive deficits such as Alzheimer's disease, confusion and forgetfulness (which could be key problems in older populations [Ryan, 1999]). The proportion of intentional and unintentional non-adherers is unknown (Barber, 2002).

However, there are some factors which are difficult to classify as intentional or unintentional. For example, a patient may omit a dose of their medication because they feel too unwell to take it. This example could be classified as intentional or unintentional non-adherence. The financial cost of medication is a factor which may lead to poor adherence, though it is difficult to categorize this as intentional (when individuals choose to spend their money on something else) or unintentional (when

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individuals do not have the required amount of money). Financial cost is not relevant to older patients in the UK because there are free prescriptions for all over the age of 60. The inconvenience of a particular medication regime is also difficult to categorize as intentional or unintentional because the inconvenience may result in an intentional choice not to take the medication, or it may mean that a patient is unintentionally unable to follow instructions. This is similar to the problem of side effects, which may render the patient physically unable to take medication due to suffering its unpleasant effects (e.g. vomiting) even though the patient wants to take their medication. While it is important that both intentional and unintentional reasons are taken into account when trying to find ways to improve adherence, it is possible that this distinction is too simple and other reasons for non-adherence are therefore missed.

Further investigation of the distinction between intentional and unintentional non-adherence to medication for chronic conditions has produced some interesting findings. Gadkari & McHorney (2012) wrote a paper titled 'unintentional non-adherence to chronic prescription medications: How unintentional is it really?' These authors studied adherence to medication in 24,017 adults with at least 1 of 6 chronic conditions. These were asthma, hypertension, diabetes, hyperlipidemia, osteoporosis and depression. Both types of non-adherence were measured (intentional and unintentional). Importantly, unintentional non-adherence was predicted by:

- Patients' beliefs about the necessity of medication
- Their concerns about taking it
- Their concerns about affordability.

This demonstrates that seemingly careless/unconscious behaviours are related to beliefs. The findings from this paper suggest that unintentional non-adherence may reflect intentions.

Numerous studies have demonstrated that communication and the doctor–patient relationship influences adherence to medication (Lau et al, 2008; Young & Oppenheimer, 2009). It is logical that the relationship between doctor and patient,

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including the way they communicate, is of utmost importance when influencing adherence to medication, because it is vital that both parties understand each other. It is important that patients feel able to discuss any concerns about the medication they have been prescribed. The importance of this relationship was confirmed by a meta-analysis whose authors concluded that good doctor-patient communication is correlated with patient adherence to treatment (Zolnierrek & Dimatteo, 2009). These findings indicate that interventions to promote adherence should focus on improving communication between patients and health care professionals (HCPs).

The number of medications a patient is currently prescribed is likely to have an influence on medication adherence. It is expected that an increased number of medications with varying administration instructions is a barrier to adherence because of the complexity of following multiple medication regimes. This is particularly relevant to older people, who are likely to have multiple co-morbidities. Roth & Ivey (2005) conducted a telephone interview study with 100 elderly patients and found the mean number of prescribed medications was 9.6. Adherence to these medications was low at 53%, but this percentage varied according to the type of medication prescribed.

Previously researchers have investigated the rate of adherence to placebo medications, with some interesting findings. There is some evidence to suggest that adherers tend to have better health outcomes than non-adherers (Simpson et al, 2006). Patients who adhered to a placebo medication tended to have better health outcomes (including mortality rates) than those who failed to take the placebo as prescribed. This is known as the healthy adherer effect. There are mixed findings of the healthy adherer effect in osteoporosis patients. In the fracture intervention trial, patients who were adherent with their placebo medication had a lower risk of hip fracture than those who took less of their medication (Curtis et al, 2011). Fracture risk was ascertained by t-scores and BMD. The authors concluded that adherence could be a proxy measure for other factors related to bone health, e.g. adherent patients may be more likely to engage in other behaviours to prevent fracture, such as physical activity. However, (Caderette et al, 2011) did not find any evidence for the healthy adherer effect in osteoporosis patients.

Another possible explanation for the placebo effect is perhaps the characteristics of people who adhere to medication may be different to those who are non-adherent, e.g. patients who follow their doctor's advice are more competent and able to follow instructions. Perhaps adherent patients are more likely to follow doctors' advice about healthy behaviours in general, not just regarding medication-taking. In other words, it is possible that adherers have better health outcomes due to their compliant nature, or their ability to control their own health behaviour, in addition to the pharmacological components of the medication. Another possible explanation is that those who have positive outcome expectancies are more likely to be adherent with treatment recommendations (Rudy et al, 2009).

2.6 Adherence to osteoporosis medication

The rate of non-adherence to osteoporosis medication is similar to the rates reported for other chronic medical conditions such as cancer, heart disease as well as for mental illness (Horne et al, 2005). Despite the ability of current medical preparations to reduce the risk of fracture, several systematic reviews conclude that adherence to osteoporosis treatment is lower than required for sufficient protection from fractures (Gleeson et al, 2009; Cramer et al, 2007; Imaz et al, 2010). A meta-analysis including more than 50,000 study participants has shown that adherence to osteoporosis medication is 48% (Kothawala et al, 2007), whereby medication was taken on 48% of the days it was required. It has been estimated that after the first year of treatment, only 45% of patients continue to take their medication as prescribed by their doctor (Solomon et al, 2005). A more recent systematic review estimates adherence to osteoporosis medication to be between 41% and 76% and persistence at one year was estimated to be between 39% and 67% (Gleeson et al, 2009). The adherence rates in these reviews are a cause for concern. Further, it is estimated that adherence rates are lower for conditions with no daily symptoms (Osterberg & Blaschke, 2005). Finally, research studies are likely to overestimate adherence (as discussed in the measurement section), therefore the actual adherence rates could be lower.

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A serious direct consequence of failure to adhere to osteoporosis medication is a fracture. Many studies have demonstrated that lack of adherence leads to a greater chance of sustaining a fracture (Caro et al, 2004; Huybrechts et al, 2006; Blouin et al, 2008). For example, in a large cohort study of over 21, 000 female participants with osteoporosis, 41% were found to be non-adherent to alendronate or risedronate (Blouin et al, 2008). These authors also reported that women over 80 years of age who did not take their medication were at a 48% greater risk of fracture when compared to those who were adherent. A study which included a systematic review and meta-analysis demonstrated that fracture risk is increased by 46% (n=171,063) if a patient is not adherent to their medication regime (Imaz et al, 2010). This increased fracture risk is the justification to find a way to assist patients with medication adherence.

A further cause for concern for osteoporosis patients is that one group of researchers found adherence to osteoporosis treatment to be worse than medication adherence in other chronic conditions, such as diabetes and hypertension (Briesacher et al, 2008). A possible reason for this low level of adherence is that patients' do not perceive osteoporosis as a serious condition (Rimes et al, 1999). A study of 956 patients with osteoporosis indicated that after seven months, almost a quarter of them had terminated their medication-taking (Tosteson et al, 2003). Gadkari & McHorney (2012) compared adherence across six chronic diseases and found that osteoporosis had the highest level of unintentional non-adherence. Further research is needed to ascertain the reasons for this low level of medication adherence. Following on from this, interventions need to be designed to improve adherence, ultimately for patients to get the desired improved health outcomes from their medication, in order to prevent their health from deteriorating and consequently to stem the waste of NHS resources.

2.6.1 Determinants of non-adherence to osteoporosis medication

Many researchers have investigated the influence of demographic factors on adherence to osteoporosis medication. As shown in other medical conditions, there are no consistent links between demographic variables and adherence to osteoporosis medication (Solomon et al, 2005). Identifying the demographic predictors of non-adherence might be useful in identifying patients who are likely to be non-adherent.

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Possible demographic and clinical predictors of non-adherence to osteoporosis medication include: age, number of co-morbidities, dosing frequency, inconvenience of the medication regime, side effects. These factors will be examined below, as well as the influence of the doctor-patient relationship and the media.

Non-modifiable determinants

There are mixed findings as to whether age is related to osteoporosis medication adherence. In many studies, age was not associated with non-adherence (Lo et al, 2000; Downey et al, 2006; Carr et al, 2006). Increasing age was associated with higher adherence in some studies (Recker et al, 2005) and lower adherence in others (Solomon et al, 2005). Older people often have multiple co-morbidities resulting in them having to take many different medications (Briesacher et al, 2008). This makes their medication regime more complicated and more difficult to adhere to. Lack of adherence in older people is likely to have worse outcomes (Myers & Midence, 1998) which highlights the importance of further research in this area.

The number and type of illnesses an individual is prescribed medication for are believed to be predictors of adherence to osteoporosis medication. Briesacher et al, (2008) conducted a study to compare the literature on adherence for seven diseases: hypertension, diabetes, hypercholesterolemia, hyperparathyroidism, gout, seizure disorders and osteoporosis. Adherence to osteoporosis medication was 51% and it decreased as co-morbidity increased. Adherence to osteoporosis and gout medication was lower compared to the other medical conditions, possibly because these diseases are generally thought to be less serious than the others in the study. Similarly, Penning-van Beest et al, (2008) reported that as the number of co-medications prescribed increased, osteoporosis medication adherence decreased.

There are many osteoporosis medication related factors which can influence adherence to medication. There are numerous studies demonstrating that dosing frequency of medication has been shown to influence adherence in osteoporosis patients (Rabenda & Reginster, 2005; Penning-van Beest et al, 2008). Medications which do not have to be taken daily could be one answer to the problem of poor

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adherence to medication. However, there is mixed evidence as to whether reducing the dosing frequency from daily to weekly improves adherence. A number of studies show improved adherence to weekly rather than daily dosing regimens (Rabenda & Reginster, 2005; Carr et al, 2006; Cramer et al, 2007). However, although adherence was better, it was still sub-optimal with a weekly dosing frequency. A more recent study with a large sample has shown that dosing frequency was not a significant predictor of adherence when other variables were controlled (McHorney et al, 2008).

Reducing the dosing frequency may improve low adherence, but it does not completely solve the problem, possibly because weekly doses are still fairly regular. Yearly doses of zoledronate are available to NHS patients, but only those with a special need for this medication e.g. severe osteoporosis or difficulty swallowing tablets. Patients who are prescribed zoledronate are required to attend a hospital appointment for a 15-20 minute intravenous infusion once a year, rather than having the burden of following a strict medication regime every day/week. However, yearly doses may also have adherence problems, as a patient still needs to remember to get their dose each year. In a study that assessed adherence to zoledronate, only 64% of patients who had received their first infusion returned for their second infusion a year later (Lee et al, 2012). This shows that dosing frequency is not the only issue of relevance to patient adherence.

A further medication related factor is the complex administration procedure for osteoporosis medication. This has been shown to influence a patient's medication-taking (Lau et al, 2008). Some osteoporosis medications require the patient to modify their behaviour after taking the medication. For example, some prescriptions require the patient to fast for 2 hours before and after taking it, or to remain upright for one hour after taking the medication. This makes the medication inconvenient and requires organisation and planning.

There is strong evidence to suggest that the side effects related to osteoporosis medication predict non-adherence (Carr et al, 2006; McHorney et al, 2007; Lau et al, 2008). Bisphosphonates can result in gastrointestinal upset and joint pain and

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strontium ranelate can lead to diarrhoea and memory loss. Given that osteoporosis is asymptomatic, it is unsurprising that patients would choose to stop taking a medication that was giving them additional discomfort. This issue is discussed further detail in chapter 5.

Modifiable determinants

Whereas clinical and demographic determinants of adherence are mainly non-modifiable, there are factors related to adherence which are amenable to intervention. For example, doctor-patient communication has been demonstrated to be a factor in adherence to osteoporosis medication. Lau et al (2008) carried out a qualitative study to investigate patients' reasons for low adherence to osteoporosis medication regimes. Patients reported that a good relationship with their doctor was needed, this enabled them to contact their doctor to discuss problems with their medication regime.

Patients' perceptions of their disease and treatment are likely to be shaped by communication from healthcare workers. This shows how the problem of non-adherence can be doctor/organisation centred as well as patient centred. 'The patient must understand the problems presented by impending bone loss and appreciate his or her personal involvement in the solution' (Gold et al, 2006, p26). In addition, communication about how medication impacts on fracture risk is also likely to be important. Interventions to improve adherence must find a way to communicate the important role of self-management in osteoporosis care. Osteoporosis is a condition which is chronic, asymptomatic and self-managed, therefore clear communication from health care professionals to patients of the fracture risks involved in the condition are essential. Previous research suggests that interventions aiming to improve communication between HCPs and patients might increase the uptake of osteoporosis preventative behaviours such as adherence to medication.

McBean et al (1994) reported that there is a need for the risks in osteoporosis to be communicated effectively to its sufferers. Recognising that conversations about medication are a type of risk communication is useful, because it highlights the

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complexity of the conversation and the difficulty of the communication. Following on from this, future interventions to improve adherence to medication could work on finding the best way to communicate the increased risk of fracture which exists when a patient does not take their medication as prescribed.

A possible mechanism for the influence of doctor-patient communication on adherence has been suggested in a study of the predictors of the patients understanding the perceived need for osteoporosis medication (Schousboe et al, 2011). It was found that patients' trust in their physician was directly related to their perceived need for medication, whereas open communication and physician's decision making style were indirectly associated with perceived need. Physicians' decision-making style and communication were directly related to patients' trust in the physician. This demonstrates the need for effective doctor-patient communication and shows that if a patient trusts their physician they are more likely to perceive a need for their prescribed medication.

A final noteworthy issue which may influence a patient's decision to initiate or take osteoporosis medication is the publicity the medication receives, regarding the risks associated with medication. The media recently reported that osteoporosis medication doubles the risk of oesophageal cancer (Green et al, 2010), but a close look at the above study reveals that the authors admit that there is no certainty that the patients who developed oesophageal cancer actually took the medication, only that they were prescribed the medication. When studies report harmful effects of medication and the media publishes them without reporting the full story, it can cause patients to make bad decisions based upon misrepresented information. A more scientifically robust study reported no association between bisphosphonate use and oesophageal cancer (Cardwell et al, 2010).

A further set of potentially modifiable determinants of adherence are patients' beliefs, motivation and emotions. These are likely to be influenced by doctor-patient communication and the media, discussed in this section. The literature of the role of

psychological factors and adherence to medication will be the focus of a critical review in chapter 5.

2.7 Summary

Adherence to medication is viewed as a behaviour which needs to be improved. While osteoporosis is a serious disease, it is well documented that its sufferers do not take their medication as prescribed, therefore reducing its therapeutic benefit. This chapter has emphasised the severity of the problem of low adherence to osteoporosis medication, particularly the resultant lack of protection against fragility fractures. To reduce the problem of low adherence, interventions are required, particularly for conditions when an effective treatment is available (Horne et al, 2005). This is particularly true for silent conditions, where there are no physical signs of the condition, which may contribute to low adherence.

This chapter provided a review of the determinants of non-adherence. There are numerous factors which influence adherence to medication; at the patient, HCP and system level (Miller et al, 1997). Studies of the relationship between demographic variables and adherence have not been able to identify the causes of the non-adherence to date. As well as an understanding of patients' beliefs about their illness and medication, there is a need to gain understanding of the psychological factors that underpin non-adherence to osteoporosis medication. This will be the focus of a critical review in chapter 5.

It is clear that there is a need for interventions to improve the way the health risk associated with not taking medication is communicated. As well as a need for interventions to improve adherence, there is a need for qualitative work to gain a deeper understanding of osteoporosis patients' illness and medication beliefs, as this will give insight into the specific beliefs which could be altered to improve adherence. The following chapter will introduce some of the psychological theories of health behaviour change which might be usefully applied to the problem of low adherence to medication.

3 Interventions to promote osteoporosis medication adherence: The role of health psychology theories

Chapter overview

Existing theories of how patients understand their medical condition and risk will be the topic for the current chapter, which presents the theoretical frameworks which could be usefully applied to the problem of low adherence to medication. This chapter is in 3 main sections. Previous psychological/behaviour change interventions which have been developed to reduce osteoporosis medication non-adherence will be discussed, before exploring the theories which could potentially be applied to this problem. Following this, the limitations of these interventions will be presented. The next main section is a review of the risk perceptions literature; given that risk perceptions are central to many health psychology theories. The final section will discuss the theories of behaviour change which have been applied to the problem of low adherence to medication.

3.1 Previous interventions to promote osteoporosis medication

Given that medication is the most common medical intervention (Horne et al, 2005), low adherence reveals a failure in the delivery of healthcare. While healthcare practitioners have no direct control over their patients' health related behaviours, they have the ability to try to influence them to change and adopt more healthy behaviours (Rollnick et al, 1999). While many interventions have been tested to improve adherence across a variety of chronic illnesses, few have been effective (Haynes et al, 2008). This ultimately means that patients cannot achieve the most therapeutic benefit possible from their medication. In the case of interventions that have been moderately successful, the reasons for success are difficult to identify (Campbell et al, 2000; Redfern et al, 2011). Improving adherence in osteoporosis patients would significantly reduce fractures, resulting in better health and quality of life, reduced admissions to hospital and a decrease in healthcare costs.

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There have been four recent systematic reviews of the effectiveness of interventions designed to improve adherence to osteoporosis medication (Crammer et al, 2007; Gleeson et al, 2009, Imaz et al, 2010; Hiligsmann et al, 2013). Some examples of the behaviour change techniques employed in these interventions include: nurse monitoring of adherence (Clowes et al, 2004), an osteoporosis education leaflet (Guilera et al, 2006) and a motivational interviewing and telephone reminder intervention (Cook et al, 2007). There have also been interventions to improve doctor-patient communication during medical consultations (e.g. Shu et al, 2009). Authors who reported improved adherence appear to have used longer follow-up of adherence than those that did not (Gleeson et al, 2009), although the exact length of time patients should be followed-up is still unknown. This means that research designs could be improved by incorporating a longitudinal focus. The following will discuss some of the adherence interventions introduced in this paragraph.

The use of an educational intervention to improve adherence to medication has been tested (Guilera et al, 2006). The experimenters gave osteoporosis patients an educational leaflet to promote medication adherence. It was found that while patients understood the educational leaflet and reported that it increased their health awareness, it did not improve their adherence. This study suggests that education alone is not enough to have an effect, because raising awareness of the importance of behaviour change did not improve adherence behaviour. It is indicated that a more complex adherence intervention is required.

Monitoring is viewed as an effective method to improve adherence to medication (Cummings et al, 2002). A nurse monitoring intervention produced some positive results in a hospital inpatient population (Clowes et al, 2004). This intervention consisted of two experimental groups. In group A, patients medication-taking was monitored by nurses. Patients in group B received the same care as group A, with an additional component of feedback about whether their condition was improving. Adherence was measured using an electronic pill counter and it was found that patient adherence was 68% in group A and 63% in group B in comparison to 42% in the control group. The close level of monitoring used in this intervention was possible because the

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patients were hospitalised. This would not be feasible for outpatients. More practical methods for improving adherence for outpatients are needed.

More recently, motivational interviewing has been used to counsel patients about medication adherence. Motivational interviewing (MI) is a recommended behaviour change technique of guiding patients to draw on their own motivation for engaging in health related behaviour (Rollnick et al, 1999). MI has improved adherence to medication for patients with AIDS (Dilorio et al, 2008) and hypertension (Ogedegbe et al, 2008). MI interventions have also been employed for patients prescribed osteoporosis medication. These studies are described below.

A telephone counselling intervention to improve adherence to osteoporosis medication was successful (Cook et al, 2007). This was a multi-factorial intervention in which nurses were trained to counsel osteoporosis patients about their goals for treatment, to assess thoughts and feelings which may act as barriers to adherence and to help patients to build and maintain motivation to engage in taking their medication as prescribed. Nurses also provided patients with education about osteoporosis. Patients received a written progress note after each telephone call from their nurse. The authors make the point that while the benefits of motivational counselling in behaviour change are well known, it is not widely used in adherence research, even though there is a strong need for behaviour change in this area. It should be noted that while this study was found to be beneficial in improving adherence, it did not have a control group. Effects were compared with non-participants, which makes it difficult to determine the impact of the study. Finally, this intervention appears to be very labour intensive and perhaps not possible in the context of the NHS. It would be beneficial to test a brief version of this intervention for effectiveness.

A more recent trial of MI was conducted, called the osteoporosis telephonic intervention to improve medication adherence (OPTIMA) trial. While osteoporosis medication adherence increased in the intervention group, the results were not statistically significant (Solomon et al, 2012). The authors of the OPTIMA trial conclude that even though the results were not statistically significant, they were clinically

relevant because adherence was 8% higher in the intervention group than the control group, which would lower the risk of fracture for some patients. Before employing the method of MI as a behaviour change technique to promote adherence, it would be beneficial to ascertain the extent to which motivation is related to adherence. It is unclear whether a brief, less intensive version of the OPTIMA trial would be effective in increasing adherence.

It is well known that interventions to enhance adherence need to be complex in order to be effective (Dunbar-Jacob et al, 1995; Haynes et al, 2008). Complex in this context means that the intervention should consist of multiple components. Interventions are also more likely to be effective if they are tailored to the needs of the individual (Haynes et al, 2008). A systematic review has shown a combination of the following behaviour change techniques to be successful in increasing adherence to medication: information (verbal or written), reminders, reinforcement, counselling, telephone follow-up and other forms of monitoring (McDonald et al, 2002). However, it is not clear which techniques should be included in an intervention to increase adherence to osteoporosis medication.

3.1.1 Limitations of former adherence interventions

While behaviour change techniques which are likely to increase adherence have been identified, the combination and intensity of these techniques required to improve and maintain adherence is still unknown (Haynes et al, 2008). Systematic reviews assessing interventions to promote medication adherence show that flawed research methodologies have been used in the majority of previous studies (Crammer et al 2007, Gleeson et al, 2009, Imaz et al, 2010). The most recent Cochrane review of interventions to improve adherence concluded that, 'current methods of improving adherence are mostly complex and not very effective, so that the full benefits of treatment cannot be realized' (Haynes et al, 2008, p2). There is a need for improved research methods in adherence intervention design.

Despite guidelines stating the importance of tailoring interventions to meet patients individual needs (WHO, 2003), it seems that few authors of intervention studies to

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improve adherence to osteoporosis medication used tailoring. There is a need for the authors of psychological interventions to select behaviour change techniques which focus on the needs of individual patients, in order to be effective (Haynes et al, 2008). For example, tailored education which is designed based upon the needs of the individual may be an example of this.

Gleeson et al (2009) identified some problems with previous research methods used in the design of osteoporosis medication adherence interventions in their systematic review of interventions: lack of tailoring, poor selection of outcome measures, lack of double blinding, lack of theory-based interventions and lack of evaluation. Only one of the seven studies included in the review used double blinding, which is a requirement of randomised controlled trials, to reduce potential bias. Further, only one study in Gleeson's review contains data for the total number of fractures participants had sustained. Similarly, another systematic review showed that many interventions did not include the number of fractures as an outcome measure (Imaz et al, 2010). However, this would require an intervention with a long term follow-up period, which is a challenge for researchers. However, these oversights in research methodology could mean these studies were not able to yield robust results and consequently our knowledge of what is effective is sparse.

To date there have been no studies which have explicitly used health psychology theory to underpin interventions to improve adherence to osteoporosis medication. The benefit of using a theory to inform the design of behaviour change interventions is the provision of clear guidance for how to do so, as well as a theoretical rationale for selecting the intervention components. It is difficult to measure the effective ingredients of an intervention to promote adherence if the intervention components are not clearly defined from the outset of the study. Previous interventions to improve adherence to osteoporosis medication have not been sufficiently evaluated, so it is difficult to determine the effective components of these interventions, as well as the elements which were not relevant/needed (Gleeson et al, 2009). No previous interventions used the MRC's framework for the design and evaluation of complex interventions (Campbell et al, 2000); which emphasises the importance of

interventions with evaluation built into their design. This is important because there is no benefit in repeatedly running complex behaviour change interventions when some components are ineffective.

In summary, while some previous interventions to promote osteoporosis medication adherence have had limited success, the reasons for any improvements in adherence are poorly understood. It would be beneficial to design an adherence intervention for osteoporosis patients based upon the MRC's framework for the design and evaluation of complex interventions. The active ingredients of effective interventions need to be identified so that these interventions can be rolled out across the healthcare service, to improve health outcomes for osteoporosis patients. The following sections will introduce a number of health psychology models, which may be beneficial for informing the design of adherence interventions.

3.2 Health psychology theories and their utilisation for improving adherence

Many health psychologists view the current bio-medical model dominant in healthcare as reductionist (Engel, 1977). While the biomedical model includes the role of biological processes and their impact on health, there is no accounting for the role of psychological or social factors. Health psychologists argue for the adoption of a biopsychosocial model in healthcare, which accounts for the influence of factors other than purely biological processes on health. This section will focus on the psychosocial factors which can influence health behaviours.

Using psychological models of health behaviour to investigate non-adherence to medication may reveal innovative solutions to the problem of low adherence. It has recently been said that 'understanding the mental models of osteoporosis, fractures and the medications recommended to reduce their risks of fractures that patients employ when weighing the risks and benefits of treatment is critical if we are to make better progress in reducing non-adherence with fracture prevention medication'(Schousboe, 2013, p26). This section will also describe a selection of the health psychology theories which have been used to describe and explain health

related behaviour and inform interventions for behaviour change processes. It is well documented throughout the health psychology literature that health related behaviour change is difficult to achieve. Using theory to investigate behaviour change might be beneficial because it can enable a systematic investigation of the particular psychological constructs relevant to the target behaviour. These health psychology theories will be discussed, because they could be used in the design of an intervention study to improve adherence to medication.

Psychological models of behaviour are used to explain and predict how individuals will react to risk information. They are used within the field of health psychology to investigate how individuals will respond to being diagnosed with a physical illness, or whether individuals will engage in health protective behaviours such as medication adherence. There are two types of behaviour change theories; cognitive science and socio-cultural (Berry, 2004). The cognitive science approach investigates behaviour at the level of the individual and suggests that individual's risk perceptions (which are seen to be formed individually rather than as members of a group) will determine how they respond to risk information. In contrast the socio-cultural approach views risk probabilities as socially and/or culturally constructed and so takes into account the broader social context in which they exist (Lupton, 1999).

3.2.1 Risk perception: a central theme in health psychology theories

The perception of risk is central to many health psychology theories. There are many definitions of risk perceptions, such as 'the subjective judgement that people make about the characteristics and severity of a risk' (HSE, 2009, p2). Generally definitions of risk perception include a combination of both the likelihood and the severity of the risk as factors relevant to the perception of risk. Risk perceptions are believed to be the psychological determinants and primary motivators for health related behaviours in many health psychology behaviour change theories (Brewer et al, 2004; Floyd et al, 2000).

Health psychology theories are based upon the underlying assumption that decisions about health are made through systematic cognitive processing of the relevant health

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information (Brewer et al, 2007). In other words, people assess whether to engage in a given health behaviour (such as a vaccination) by assessing their level of risk. Therefore a perception of high risk is expected to be an important motivator for health protective behaviour.

The measurement of risk perception is difficult. Slovic (1987) used psychometric tests to measure risk perceptions and produced cognitive maps of risk attitudes and perceptions. He identified the factors involved in the recognition of risk as the following; familiarity, control, catastrophic potential, equity and level of knowledge. He used factor analysis to identify three levels of subjective risk perception which were 1) dread risks (where consequences were fatal), 2) unknown risks and 3) the number of people exposed to the risk. It has been suggested that individuals' risk perceptions and judgements about risky behaviours are influenced by their emotional response to the risk (Loewenstein et al, 2001). It is now generally accepted that although we can try to measure risk perception, it is a subjective experience (Slovic, 2010). Affect may explain why people engage in unhealthy behaviours despite knowing they are harmful, e.g. smoking.

An interesting point about risk perception is the common finding that people often estimate their own level of risk as lower than that of other peoples. They take the view that they are less likely to have negative experiences and more likely to have positive experiences in comparison to others. This phenomenon has been termed "optimistic bias," "comparative bias" or "unrealistic optimism" (Weinstein & Klein, 1996). While optimism is beneficial in so far as it can mean people do not worry unnecessarily, it could make people more likely to engage in risky behaviour because they believe they have less chance of it resulting in hazardous outcomes. In other words people tend to underestimate their level of risk in comparison to others, which could mean they do not believe there is a need to take precautions to protect themselves against poor health outcomes. This has been shown to be true for beliefs about the risk of contracting many diseases including cancer (Fontaine and Smith, 1995). Optimistic bias has been noted as a barrier to effective risk communication (Weinstein, 1989; Berry, 2004).

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The first studies conducted to investigate optimistic bias were carried out on samples of young college students and younger adults. However, recent studies have suggested that optimistic bias is present throughout an individual's lifespan (Renner et al, 2000). This is useful knowledge and it shows that public health campaigns could work on reducing optimistic bias in order to make risk perceptions more accurate, with the aim of promoting health related behaviour or reducing risky behaviour. The implications of the phenomenon of optimistic bias is that risks should be communicated in a way that highlights personal risk and makes the risk information less general and more specific to the person.

The relationship between risk perceptions and behaviour is bidirectional, therefore the cause and effect is difficult to evaluate. "Risk perceptions can affect protective behaviour and protective behaviour can affect risk perceptions" (Brewer et al, 2004, p125). The relationship between these variables is intricate and reciprocal and is best examined using longitudinal study designs rather than cross-sectional (Brewer et al, 2004).

Some key questions are; how do risk perceptions influence health behaviour and is aiming to change risk perceptions likely to be a successful strategy for changing behaviour? (Wright, 2010). Wright's review of the literature indicates that there is a small yet significant relationship between risk perceptions and behaviour. Wright also notes that the strength of this relationship may be stronger than has been found in research to date because of the methodological challenges of measuring risk perceptions. Similarly, a recent meta-analysis of behaviour change interventions concluded that increasing risk perceptions does change intentions and behaviour (Sheeran et al, (2013), particularly when the intervention targeted both a) an individual's perceived level of threat and b) their perceived ability to deal with the threat. An important question which arises from Sheeran's meta-analysis is; how can perceptions of risk be increased in order to aim to change behaviour?

3.2.2 Perceptions of risk for osteoporosis and fractures

The risk of fracture in osteoporosis is particularly difficult to communicate and comprehend, because everyone carries a certain level of risk for sustaining a fracture. For example if an individual was in a serious accident, e.g. road traffic accident, they may sustain a fracture regardless of whether they have osteoporosis. This is perhaps why it is difficult for osteoporosis patients to understand their level of risk of fracture in comparison to others who do not have osteoporosis.

Hvas et al (2005) studied healthy women's awareness of the risk of osteoporosis in a qualitative study and found that patients who felt worried about their risks were more likely to engage in osteoporosis preventative behaviours. This study used fear appeals, by providing information to raise patients' awareness of the health threat. The authors suggest that fear appeals can be beneficial in producing behaviour change, although there are ethical concerns about using fear appeals. On the contrary, it seems just as unethical to fail to give patients the full information available about their health and how to maintain it in the clearest way possible. Future work is required to determine how patients respond to risk information about their condition.

Qualitative studies have been conducted to assess patients' thoughts and beliefs about their fractures (Meadows & Mrkonjic, 2003; Meadows et al, 2004). It was found that fracture patients believed that once a patient other than themselves had sustained a fracture, they were more likely to have another fracture. However, these fracture patients believed that they themselves were at less risk of sustaining a subsequent fracture in comparison to other patients. This provides evidence for patients with osteoporosis displaying optimistic bias, or having difficulty understanding their levels of risk in osteoporosis.

Similar studies have been conducted to investigate patients' perceptions of their fracture and future fracture risk (Giangregorio et al, 2008; Giangregorio et al, 2009). It was found that half of the osteoporosis patients in the study who had sustained a fragility fracture did not know or understand that they were at an increased risk for a future fracture; they also did not perceive the need to take their prescribed medication

for osteoporosis. These findings are important and perhaps indicate a failure in the communication of risk, in so far as either healthcare professionals are not communicating these patients' risks to them effectively, or the patients have great difficulty in comprehending these risks. It is expected that lowered risk perceptions in osteoporosis could contribute to medication non-adherence. If patients do not understand their risks then they cannot behave in the appropriate manner to minimize these risks. More research is required to investigate this further, to determine the relationship between risk perceptions and adherence.

3.2.3 Social Cognition Models

Social Cognition Models (SCMs) were developed by social psychologists and can be seen as psychometric risk models which can be used to explain and predict behaviour and behaviour change (Conner & Norman, 2001). The SCMs are models of how cognitions influence behaviour and were devised in recognition of the need to understand behaviour in a social context (Rutter & Quinne, 2002). SCMs are also known as expectancy-value models, they suggest that individuals select their behaviours based upon the expectancy of the outcome and the value they place on it (Conner & Norman, 2001). The SCMs are a set of models which consist of theorised psychological determinants of behaviour and can be used to predict behaviour at a given time point (Armitage & Conner, 2000). Though developed within the field of social psychology, SCMs can also be used in health psychology to investigate how people respond to a health threat. Some examples of SCMs are provided below.

Despite differences between these models in basic factors, the social cognition models are similar in so far as they theorise that risk perceptions are the key determinants of health behaviours, in other words 'feelings of threat motivate behaviour change' (Sheeran et al, 2013, p1). Many of these theories suggest that perceived susceptibility to and perceived severity of an illness are the key cognitions involved in an individual's threat appraisal, which will predict their subsequent health behaviour (Rosenstock, 1974; Rogers, 1975). Many social cognition models have been widely applied to adherence research. The most influential and widely used social cognitive theories will

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now be discussed, including how they have been applied to the problem of low adherence to prescribed medication.

The Health Belief Model

The Health Belief Model (HBM) is an example of a social cognition model. The HBM was developed to predict health behaviour using: an individual's 'perceived severity' and 'perceived susceptibility' of a given risk, as well as the 'perceived benefits' and 'perceived barriers' to a given health behaviour (Rosenstock, 1974). Rosenstock proposed that if an individual perceives themselves to be at risk and they perceive the risk to be severe, they will act to reduce this risk, after analysing the perceived benefits and barriers of the risk reducing behaviour.

The HBM has been used to investigate individuals' beliefs about osteoporosis (Wallace et al, 2002; Cline et al, 2005). A cross-sectional questionnaire study (with osteoporotic and non-osteoporotic patients) investigated the relationship of components of the HBM with adherence to medication and HRT (Cline et al, 2005). They found that perceived susceptibility to osteoporosis and the perceived benefits of medication were related to adherence to medication. However, this paper also shows that the HBM constructs were not predictive of the use of HRT which used to be commonly prescribed to treat osteoporosis.

A meta-analysis has shown that the four constructs of the health belief model were positively correlated with adherence to medical regimens in a variety of medical conditions (Harrison et al, 1992), with the HBM predicting 10% of the variance in adherence behaviour. The positive correlations indicate that the HBM would be a useful model to use in an intervention to improve adherence to medication. However, it is difficult to conclude on this because many of the included studies had methodological flaws. However, a difficulty with applying the HBM to the problem of adherence is that the HBM implies a one-off decision or cost-benefit analysis of whether to engage in a particular health related behaviour (Horne et al, 1999).

Protection Motivation Theory

Protection Motivation Theory (PMT) is an extension of the health belief model. PMT was developed in order to explain how individuals make sense of fear appeals (Rogers, 1975). The PMT is made up of 3 psychological predictors of preventative behaviours: (a) the perceived severity, (b) the perceived probability of occurrence and (c) the efficacy of the recommended health behaviour (belief that the protective behaviour will reduce the risk). This model can also be used to gain understanding of how people respond when they are diagnosed with an illness. This model predicts that if an individual feels highly susceptible and that the illness is of high severity, the individual is more likely to have the behavioural intentions to engage in health protective behaviour; if they feel that the protective behaviour will reduce their level of risk. Protection motivation is defined as danger control (Rogers, 1975), or feeling motivated to engage in a health protective behaviour. It is also theorised that fear resulting from health risk information will impact upon behavioural intentions, though indirectly.

A meta-analysis of the PMT and health behaviours such as adherence to medication has shown that there are moderate effects on behaviour when an intervention is based upon this model (Floyd et al, 2000). It explains some of the variance in adherence behaviour, so therefore this model is likely to be useful to inform an intervention to improve adherence to medication. A problem with the PMT is that it does not explain why some health information messages are not attended to (message rejection) by individuals (Witte, 1992). A similar model to PMT is the Extended Parallel Process Model, which is described later in this chapter.

The Theory of Planned Behaviour

The theory of planned behaviour (TPB) (Ajzen, 1985) is another widely used theory of behaviour change, developed in the field of social psychology. The TPB is as an extension of the theory of reasoned action (Fishbein and Ajzen, 1975). The authors of the TPB suggest that *intentions* are the single most important determinant of behaviour, with behavioural intentions formed by attitudes (towards behaviour), subjective norms and perceived behavioural control (self-efficacy). However, there is a

gap between intentions and behaviour known as the intention behaviour gap. The TPB's authors acknowledge that the intention behaviour gap is difficult to account for.

The TPB has been widely used to investigate the problem of low adherence to medication. Abraham et al (1999) found that the TPB constructs predicted 50% of the variance in self-reported adherence to malaria medication. Reviews of adherence interventions based upon the TPB have shown mixed findings. In a meta-analysis, Hardemann et al, (2002) reviewed the use of the TPB to inform behaviour change interventions and found the results inconclusive due to methodological flaws. It is likely that the TPB has utility for adherence interventions, though more empirical work is needed to investigate this.

3.2.4 Leventhal's self-regulation model

The Self-Regulation Model (SRM) is a social cognition model which explains how an individual copes with an illness as well as the cognitive and emotional responses to an illness diagnosis or a health threat (Leventhal et al, 1984). It is theorised that cognitions and emotions are used to guide behaviour. The SRM (Figure 2) has been identified as the most logically appropriate model for investigating the problem of low adherence to medication (Munro et al, 2007). The SRM is also known as the Common Sense Model (CSM), because it is an example of a common sense theoretical model created by a patient, based upon their perceptions and understanding of their illness. Further, it is theorised that patients will engage in a particular health protective behaviour if it makes common sense and fits with their illness perception.

A major feature of the SRM is illness perceptions, defined as cognitive representations (beliefs) patients have about their illness (Weinman et al, 1996). This theory states that patients make sense of their illness by forming both cognitive and emotional representations of the illness, together called illness representations and emotional representations respectively. These representations describe how people view and make sense of their illness and exist as a parallel pair. In literature focusing on the SRM, illness representations are sometimes signified using the terms illness perceptions, illness cognitions or illness schemata, with synonymous definitions.

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Patients may hold illness representations which act as barriers to them behaving in a way to prevent/manage their illness.

Leventhal et al, (1984) proposed that patients' illness and emotional representations form a model and are used to guide their illness management/coping, so that once a person forms these perceptions of their illness, they use them to regulate their behavioural response to the illness. Self-regulation is defined as "mental and behavioural processes by which people enact their self-conceptions, revise their behaviour, or alter the environment so as to bring about outcomes in line with their self-perceptions and personal goals" (Fiske & Taylor, 1991, p.181).

According to the SRM the following distinct processes occur when a person is diagnosed with an illness or informed of a health threat; (1) interpretation (both cognitive and emotional), which leads to (2) coping, problem-focused or emotion-focused which is followed by (3) appraisal, checking if the method of coping was effective (Leventhal et al, 2010). For a summary diagram of the model, see Figure 2. In contrast to other social cognition models, the SRM is a dynamic model, meaning that an individual's appraisal of their ability to cope with a health threat/illness is continuously changing as they gain more knowledge and understanding of their illness and how to cope with it. Adherence is considered as a coping mechanism, because it is a way of managing the illness.

The SRM is a suitable model to apply to the problem of low medication adherence because it describes the psychological processes through which people cope with an illness. It is called the self-regulation model because it suggests that people go through a continual process of self-regulation (appraisal of their resources for coping and action plans) in order to manage their illness. There are two theorised processes of coping; *emotion-focused coping* and *problem-focused coping* which can occur simultaneously (Leventhal et al, 1984). These coping mechanisms have also been called 'abstract conceptual' or the 'concrete experiential' respectively. The coping mechanism is selected by a person based upon the information given about the health threat/illness and how that information is understood. Problem-focused coping

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consists of finding instrumental solutions, whereas emotion-focused coping is about managing the emotions aroused by the health threat. Problem-focused coping is suggested to be more beneficial as this is associated with finding a way to deal with the problem. Adherence to medication is an example of problem-focused coping, whereas ignoring/avoiding health threat information is an example of emotion-focused coping.

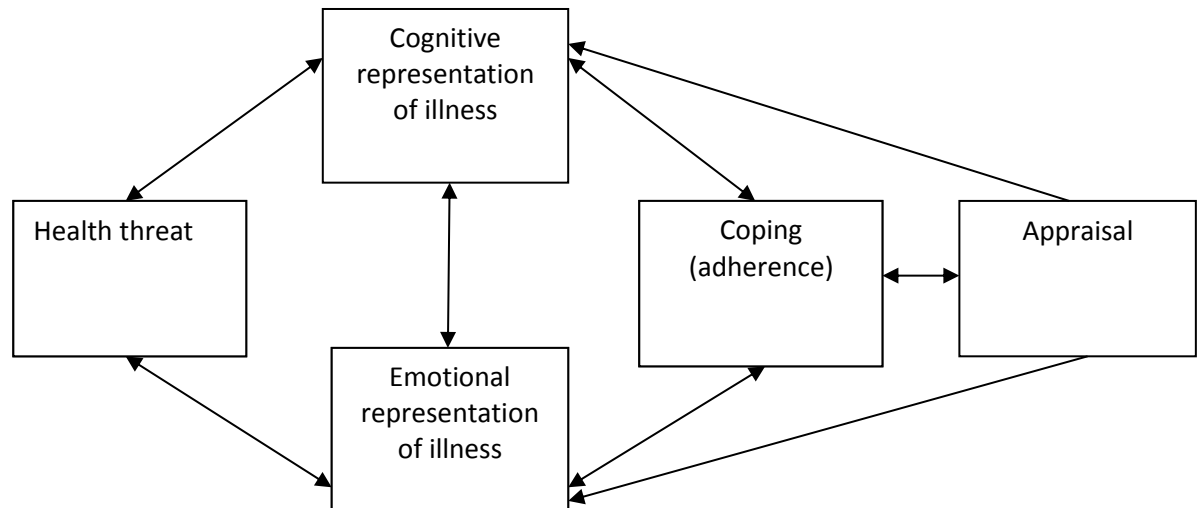


Figure 2. Self-regulation model of illness cognitions and emotions (Leventhal et al, 1984)

Cognitive Representations

Cognitive representations are influenced by cultural factors (Landrine & Klonoff, 1992) past experience and the opinions of significant others (Leventhal et al, 1992). The authors of the SRM propose that patients make sense of their illness by developing their own understanding of five features typical of any medical condition: *identity* (what is it?), *causes* (what caused it?), *consequences* (how will this affect me?), *timeline* (what is the duration of the illness?) and *control/cure* (what do I need to do to treat it?) (Leventhal et al, 1992a). It is proposed that these 5 features form a cognitive representation of the illness. A key element of this theory is that patients are more likely to be adherent with treatment recommendations if they have a coherent model of their illness – in which the illness makes sense to them. An extension of the SRM was proposed, with the inclusion of medication beliefs as an additional cognitive

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predictor of coping when the SRM is being used to explore medication adherence (Horne et al, 1999).

Emotional Representations

In addition to this cognitive process, it was proposed that patients have an emotional representation of their condition (Leventhal et al, 1984). It was theorised that the emotional response to a medical condition could influence the selection of a coping method. It was suggested that the emotional response to having a medical condition, although independent, 'can interact with and/or be part of the cognitive' representation (Leventhal et al, 1992, p158). Cameron & Jago (2008) expanded the SRM to include strategies for emotional self-regulation. They reviewed two interventions focusing on promoting adjustment and well-being when individuals were diagnosed with a medical condition. They suggest that in order for patients to effectively cope with an illness diagnosis, both cognitive and emotional representations of the condition would be involved in self-regulation.

An extension of the SRM

An extension of the SRM was proposed by Horne (1997) and presented in a study by Horne & Weinman (2002), in relation to adherence to medication in asthma patients. The SRM was extended to include medication beliefs as an additional cognitive predictor of adherence (Horne et al, 1999). They found two groups of beliefs to be associated with adherence to medication; beliefs about the necessity of taking medication and concerns about the medication. There is a type of cost benefit analysis which takes place when a patient is consciously deciding whether or not to take medication (Donovan & Blake, 1992). The strength of the belief in the necessity of the medication is weighed against the concerns about the medication (Horne, 1997). This group of beliefs is known as the necessity-concerns framework (NCF). This proposed extension SRM states that patients will assess the appropriateness of the treatment by trying to understand their own personal need for the medication and weighing this against their concerns about the medication (e.g. side effects, being dependent on the medication, overuse of medication prescriptions, harmful chemicals etc.).

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Horne et al (1999) developed the beliefs about medications questionnaire (BMQ), for the purpose of investigating the role of medication beliefs in medication adherence. This is a brief questionnaire which assesses patients' beliefs about their medication, particularly the NCF as discussed above. The BMQ has been validated as a measure of beliefs about medication and used widely in adherence research in many medical conditions.

3.2.5 Empirical support for the SRM

Questionnaires to measure the psychological constructs included in the SRM have been developed and validated and can be adapted for use in many medical conditions (Weinman et al, 1996; Moss-Morris et al, 2002). Detailed descriptions of these questionnaires are provided in chapter 7. These questionnaires make it possible to quantify the relationship between illness perceptions and various health related behaviours, such as adherence to medication. Many studies have shown empirical support for the SRM, with associations between illness perceptions and adherence. Some of these studies will be described in this section.

Overall the SRM has been used in many studies of illness behaviour, particularly in relation to how cognition is related to illness coping behaviours, such as adherence. Hagger & Orbell (2003) carried out a meta-analytic review of 45 studies to investigate the relationship between illness representations and a range of health behaviours. They detected a small yet significant relationship between coping behaviours and illness representations. Beliefs of a strong illness identity and serious consequences were associated with emotion-focused coping, whereas a strong belief in the controllability beliefs of the condition was associated with problem-focused coping. Hagger & Orbell's (2003) meta-analytic review provides evidence that illness representations are related to adherence. This shows the importance of identifying individual's illness representations before designing interventions to promote adherence to medication.

3.2.6 Application of SRM to adherence research

The most common use of the SRM to date has been to explore the illness perceptions/illness representations of patients with a given medical condition. The

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SRM has been usefully applied to the problem of poor adherence to medication in many medical conditions, in various types of studies. For example, Chen et al (2010) have used this model to gain an understanding of illness perceptions in patients with hypertension. It was found that hypertensive patients did not understand that their condition was controllable, implying that adherence may be improved by helping patients to understand that cardiovascular disease is controllable/manageable. In other words, the SRM was used to identify erroneous illness perceptions, e.g. 'there is nothing I can do to improve my hypertension', which might be amenable to change through psychological intervention.

Other studies have shown that illness perceptions can influence adherence to medication. Halm et al (2006) studied patient adherence to asthma medication. They found that over half their study participants believed that their asthma was only present at the time they experienced symptoms. Importantly, the group of patients who did not identify asthma as a chronic condition were less likely to adhere with recommendations for inhaler use. This study demonstrates how illness beliefs can influence adherence.

As previously discussed, medication beliefs have been found to be related to adherence to osteoporosis medication (Horne & Weinman, 2002). Therefore it would be expected that a theory including medication beliefs would be suitable to use in the design of an intervention to improve adherence to medication. The extension of SRM to include medication beliefs (Horne, 1997) will from now on be referred to as the extended SRM. The extended SRM was used to inform the design of interventions for patients with end stage renal disease (Karamanidou et al, 2008) and patients who have suffered a stroke (O'Carroll et al, 2013a).

Karamanidou et al (2008) carried out an innovative psycho-educational intervention, in which patients with end stage renal disease were shown a model of the kidney alongside an explanation of how the phosphate binding medication used to treat it has its effect. The intervention group demonstrated improved knowledge, increased understanding of the medication regime and increased belief in the response-efficacy

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of the medication. This demonstrates the benefits of using theory to design an intervention.

The extended SRM was used to inform the design of an RCT to improve adherence to anti-hypertensive medication for stroke patients, with good results (O'Carroll et al, 2013a). The intervention was designed based upon the MRC's framework for the design and evaluation of complex interventions. The intervention aimed to target both intentional and unintentional non-adherence, using two key intervention components. Intentional non-adherence was addressed by 'eliciting and modifying any emergent erroneous beliefs regarding the patient's medication and their stroke' (O'Carroll et al, 2010, p3). Implementation intentions, also known as if-then plans were selected to target unintentional non-adherence. Former studies by this research group found stroke patients' beliefs about medication (e.g. too many medicines are prescribed) can prevent them from adhering to their prescribed medication (O'Carroll et al, 2008). However, the authors reported that the use of electronic pill counters to measure adherence may have influenced adherence rates, because electronic pill counters make the pill bottle physically different and are a constant reminder to the patient that they are being assessed. (O'Carroll et al, 2013b).

3.2.7 Witte's Extended Parallel Process Model

Another model which could be used to explore adherence to medication is the extended parallel process model (EPPM). Similar to PMT, the EPPM states that when a person is faced with a health threat, they appraise two components of it: the level of threat and their ability to deal with it (Witte, 1992). The EPPM is based upon Leventhal's parallel process model (Leventhal, 1970). The EPPM (see Figure 3) provides a theory for situations when increasing risk perceptions *will* and *will not* result in risk reducing behaviour (Witte, 1992). Witte suggests that when people receive health risk information which implies a low risk, the message is not further processed, because it is viewed as trivial or irrelevant. However, if people feel there is a high probability of experiencing a health problem (high vulnerability/susceptibility) and that the health problem is serious (high severity) then the person will experience high fear arousal. If a

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person experiences high fear arousal, this fear could act as a motivator for the person to assess their ability to deal with the health threat.

According to the EPPM there are three possible responses to fear arousal; *danger control* (risk reducing behaviour, e.g. taking medication as prescribed) or *fear control* (denial and avoidance of the health threat), see Figure 3. Efficacy messages are theorised to predict whether an individual will engage in danger control or fear control. When perceived efficacy is greater than perceived threat, the danger control response will be initiated. To the contrary, when perceived threat outweighs perceived efficacy, the resultant response will be fear control (Witte, 1992). While PMT and the EPPM are similar, the difference is that fear arousal was assigned a more important role in the prediction of behaviour in the EPPM than in PMT. The author of the EPPM states that fear arousal alone will result in a maladaptive coping response; therefore it is important that messages of health risk do not just evoke fear. The inclusion of the role of self-efficacy in the EPPM is important and there is evidence that self-efficacy has a strong influence on behaviour (Bandura, 2004).

A meta-analysis of studies investigating the effectiveness of fear appeals concluded 'it appears that strong fear appeals and high-efficacy messages produce the greatest behaviour change, whereas strong fear appeals with low-efficacy messages produce the greatest levels of defensive responses' (Witte & Allen, 2000, p591). This means that a fear appeal attached with a motivational message (or a message with emphasis that action should be taken) is likely to produce improved health related behaviour. To summarise the implications of this theory; if a fear appeal is coupled with a message which increases self-efficacy to deal with the threat, this message would be theorised by the EPPM to result in an adaptive coping response – e.g. an attempt to minimise the risk by adherence to medication.

While the EPPM 'owes its roots' to the social cognition models, it differs from them because it theorises three potential responses to a health threat message (Witte, 1998 p573). The prediction of when a message will be attended to might be beneficial for an

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asymptomatic condition, in which risk communication of the severity of the condition is challenging. The three potential responses to a health threat message are:

“(a) the traditional response of attitude/intention/behaviour change (danger control responses)

(b) No response to the campaign due to low perceived threat

(c) Fear control responses to the campaign such as denial, defensive avoidance, or reactance. It is important to note that campaigns can fail because they are ignored, as in b, or because they produce strong effects, such as denial or reactance which interfere with behaviour change” (Witte, 1998, p573).

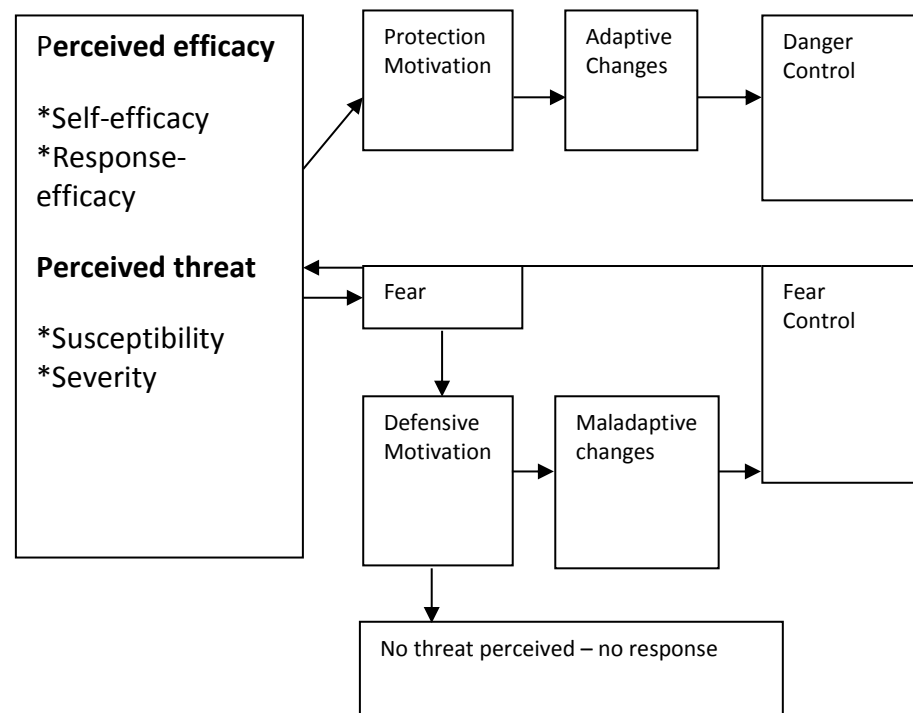


Figure 3. The extended parallel process model (Witte, 1992)

3.2.8 Application of EPPM to adherence research

Although there are many studies using the EPPM to promote health behaviours, to the author's knowledge there is only one previous investigation of the influence of the EPPM variables on adherence to medication. As well as a description of a study of

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medication adherence, the following will describe studies which investigated the role of health threat messages for: motivating testicular examination, promoting safe sex and encouraging responsible consumption of alcohol. These studies have been chosen for this chapter because, although they are not exactly about adherence, there is some similarity given that they are investigating the uptake of a new health related behaviour.

A study of adherence with a multivitamin tablet in patients with cardiovascular disease demonstrated the EPPM as a useful model for shaping health communication, in the form of an information leaflet (Mckay et al, 2004). The leaflet portrayed the severity of the disease (high threat) with a message about how to manage the threat (high self-efficacy) and was found to make non-adherent patients more confident in their ability to take their medication. The authors comment that the EPPM was useful because it focuses on how to make a message persuasive, whereas interventions based on other models focus mainly on the content of the message. However, the study did not look at the relationship between the EPPM variables and adherence. There is a gap in the literature of studies investigating the relationship between the psychological constructs of the EPPM and adherence.

The EPPM was used to design health risk information for 80 male students regarding the risk of developing testicular cancer (Morman, 2000). A health risk message was needed to inform men of the risks and motivate them to perform the testicular self-exam (TSE). Four types of health risk messages were tested in the study, two with high threat/high efficacy and two with high threat/low efficacy. Information about testicular cancer was either fact based or a narrative from a patient. It was found that messages of high threat/high efficacy increased the participants' intentions to regularly engage in TSE. When comparing the information that was fact or narrative based, there was no difference in reported intentions for TSE. This study showed the utility of the EPPM in the design of informational material to increase perceptions of risk.

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The author of the EPPM designed a fear appeal campaign to promote safe sex (Witte, 1998). The data collected from this study supported the EPPM and the author described the situations in which health campaigns are likely to fail. The study highlighted the importance of emphasising personal susceptibility to a health threat, which is a challenge for a health campaign intended for a large group of people, e.g. a national campaign. It is also commented that campaigns often fail because they fail to address the issue of response- efficacy.

A larger study (n=224) investigated the relationship between EPPM variables and college students alcohol consumption (Moscato, 2001). In this study, students were invited to a meeting where they were informed by a panel consisting of law enforcement officers and the school principal about the problem of high alcohol consumption. During the meeting students were advised to attend alcohol free events. The message was delivered in the high threat/high efficacy format recommended by the author of the EPPM. This survey found that both perceived efficacy and perceived threat were significantly associated with drinking alcohol. Further, it was found that students were more likely to attend alcohol free events if they had heard the health threat message than if they had heard about it through a secondary source. This provides evidence for designing health promotion interventions based upon the EPPM.

The low quantity of research focusing on the EPPM and medication adherence is surprising. The EPPM is particularly suited to the problem of promoting health behaviours such as adherence because it focuses on how health threat messages can be persuasive. A possible reason for this lack of research could be the ethical considerations involved in giving people information which might be frightening. This issue is discussed in further detail in study 4.

The limitations of the social cognition models

A criticism of many of the SCMs is they are based upon the assumption that people make conscious, rational choices about every health decision (Gebhardt & Maes, 2001) when in reality this is not always the case. Another problem common to the majority of SCMs is they do not take into account the role of emotions, such as fear – which are

likely to influence behaviour (Norman and Connor, 2001). Furthermore, they do not represent change as a process that occurs over time and can be criticised for being too simplistic, or relating to 'single point decisions about recommendations for maintaining health (e.g. to attend for screening)' (Weinman & Horne, 1998 p40). While many of the SCMs have overlapping constructs e.g. perceived susceptibility to an illness, the models have not been combined to form a more comprehensive model, (Armitage & Conner, 2000) which makes theory selection difficult.

3.2.9 Selection of behaviour change techniques

In the process of designing a psychological behaviour change intervention, as well as identifying the psychological constructs which require change, it is essential to select behaviour change techniques which are expected to influence the target behaviour (Michie et al, 2008). The following is the information, motivation and behavioural skills (IMB) model, a theory of the basic requirements of behaviour change (Fisher & Fisher, 1992). The model focuses on the factors that need to change in order to attempt to influence/change behaviour; information, motivation and behavioural skills (see figure 4).

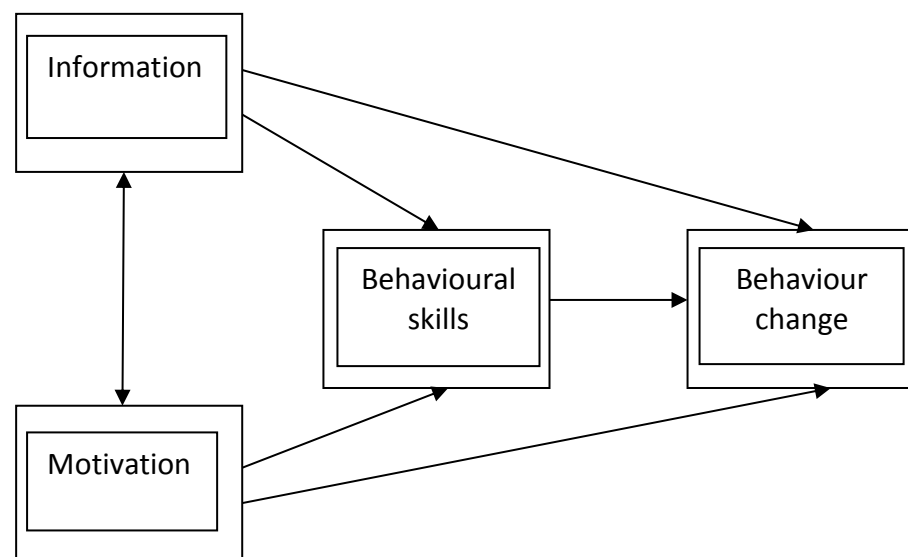


Figure 4. Information, Motivation and Behavioural Skills Model (Fisher & Fisher, 1992)

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While this model is useful for a simple description, it has little detail about the specific cognitions which may require intervention in order to attempt to influence health related behaviour. While this model provides some clues for the types of behaviour change techniques to employ, more detail is needed. This shows that more complex social cognition models are needed to inform the design of behaviour change interventions. However, this model is a useful overall guide for the selection of behaviour change techniques for an adherence (or other behaviour change) intervention.

3.3 Current Gaps in the literature

As described above, many theoretical models can and have been applied to the problem of low medication adherence, but interventions to improve adherence to medication in osteoporosis patients have not drawn on them. There is a need for research to test health psychology theories to find out which would be effective in interventions to improve adherence to osteoporosis medication. There is a clear need for theory-based interventions, because interventions with osteoporosis patients to date have been difficult to systematically evaluate, due to this lack of a theory-base (Gleeson et al, 2009).

It has been noted that the extended SRM could be used to explain patients' self-management behaviour such as their treatment choices (Hobro et al, 2006). The application of this theory to the problem of low adherence may give rise to a more detailed understanding of how people with osteoporosis make sense of their illness and medication. It is important for research to focus on understanding patients' thoughts and beliefs about their illness because they may hold beliefs about their risk of illness which act as barriers to health behaviour improvements.

There have been studies of osteoporosis patients' medication beliefs. For example, Schousboe et al, (2010) explored patients' medication necessity and concern beliefs, using the necessity-concerns framework. To the author's knowledge, there is no published research to date which explicitly used the extended SRM with osteoporosis patients to explore illness perceptions and medication beliefs. Use of the extended

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SRM allows researchers to gain insight into how patients understand their condition, which can then be used to inform interventions to improve their self-management behaviours (e.g. taking their medication, diet, exercise etc.).

It is likely to be beneficial to use theory in the design of an intervention to improve adherence, because it can allow for a systematic investigation of the reasons for non-adherence. It is logical to gain an understanding of patients' illness beliefs before providing a behaviour change intervention, because the intervention might need to include information targeted at specific knowledge deficits, e.g. lack of understanding the condition is chronic and asymptomatic. Or if a patient incorrectly believes that a disease is not treatable, this belief (which could be a barrier to behaviour change), could be modified through intervention e.g. education, motivational interviewing etc. The self-regulation framework could be useful for guiding research in this field and could provide information which will be able to guide intervention design.

There is a lack of research investigating the risk perceptions of osteoporosis patients, particularly empirical research to look at the relationship between risk perceptions and adherence to medication. To the author's knowledge there have been no studies using the EPPM in the design of an adherence intervention. Further, there are few studies which attempt to modify osteoporosis patients' illness perceptions/risk perceptions. Patients' perceptions of illness and risk need to be understood to identify inaccuracies that may be linked to behaviour. There is a gap in the literature for new methods of risk communication in osteoporosis. These could be investigated using the both the extended SRM and the EPPM as a framework on which to base the research.

3.4 Summary

This chapter highlights that even though there have been nearly four decades of research investigating the problem of low adherence to medication, there is still a need for innovative methods and more effective adherence interventions for osteoporosis patients. In summary, finding a way to persuade individuals to adopt health protective behaviours is difficult and this is likely to be due to variations in their perceptions of risk and optimistic bias. There is a need for a balance between

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interventions which will not only increase adherence to medication, but are also feasible and practical within the current climate of the NHS. The ultimate aim of this intervention would be to reduce the incidence of osteoporotic fractures.

This section has discussed the relevant theories which have the potential to inform the design of an intervention to increase osteoporosis medication adherence. These theories are about how people respond to health risk information. Two theories stand out as particularly relevant as possible elements of the solution of the problem of low adherence to medication, the extended SRM and the EPPM. It is very important that theory is used in the design of interventions to change health behaviour, because they can be clearly defined (in terms of what the intervention includes) and evaluated (in terms of the level of success of each component). The following chapter will discuss how these theories will be used to guide the present research, with a proposal for an innovative intervention to promote adherence to prescribed medication for osteoporosis.

4 The rationale for the present research

Chapter overview

This chapter will draw together and summarise the literature reviewed in the previous chapters in order to set the agenda for the research. It will summarise the limitations of previous interventions to promote osteoporosis medication adherence, proceeding to a suggestion for a new approach to investigate the problem of low adherence to osteoporosis medication. The theories which were used to investigate this problem will be summarised, with a description of how the theories were used. This chapter will justify the use of two particular theories for this thesis; the extended self-regulation model and the extended parallel process model. Diagrams are used to highlight how theory was used to inform the design of the present research. This chapter will describe how the Medical Research Council's framework for the design and evaluation of complex interventions (Campbell et al, 2000) was applied to the intervention development. This chapter will also address the proposed method to design and test the adherence intervention, particularly to justify the choice of using an N-of-1 case-series design.

4.1 Rationale for innovative adherence interventions

The documented low level of osteoporosis medication, coupled with strong evidence to indicate that adherence to medication can significantly reduce fracture risk, provides the scientific justification for further research to focus on promoting osteoporosis medication adherence. Moreover, many of the methods used to measure medication adherence provide overestimations of adherence, which suggests that in practice adherence may be lower than the research literature suggests (Haynes et al, 2008). The issue is of particular importance when considered in the context of the rapidly aging population.

Previously, many behaviour change interventions were not fully defined or developed (Campbell et al, 2000). Without clear definition or evidence-based development, it is difficult to provide evidence of the effectiveness of the intervention in order to implement it on a larger scale. Before designing interventions to improve adherence,

there is a need to gain understanding of the determinants of adherence through empirical research. In particular, it is likely to be beneficial to gain understanding of the strength of the relationship between these determinants and adherence.

While many interventions have previously been developed to improve adherence, they have been limited in their success because they are not theory-based, well developed or sufficiently evaluated. There is a clear need for studies to evaluate the intervention components and mechanisms of change. Better quality interventions, which use the best measures of adherence possible, including the number of fractures as an outcome measure are required (Gleeson et al, 2009). Interventions which are found to improve adherence to osteoporosis medication could then be adapted for use with patients with other medical conditions.

Given the lack of multi-dimensional evaluation of previous interventions, the design of future behaviour change intervention studies should include plans for evaluation (Campbell, 2007). The majority of interventions previously carried out with an aim to improve adherence have been randomised controlled trials. An innovative approach to investigate low adherence to medication is to use a different research method such as an N-of-1 design that would allow for in-depth investigation of non-adherence with a small sample of patients. Further, this design would allow each component of the intervention to be evaluated in detail. While the findings from this type of study could not be generalised to the population, a case study has the potential to determine which components of an intervention are effective. The use of an N-of-1 case-series approach to study adherence to medication is a novel method to investigate this problem and would be an original contribution to the health psychology literature.

4.2 Medical Research Council guidelines for complex interventions

The Medical Research Council (MRC) has published guidelines for the design and evaluation of complex interventions in order to ensure an evidence-base for interventions of high quality and effectiveness (Campbell et al, 2000; Campbell et al, 2007), see Figure 5. These guidelines state the importance of building an evidence

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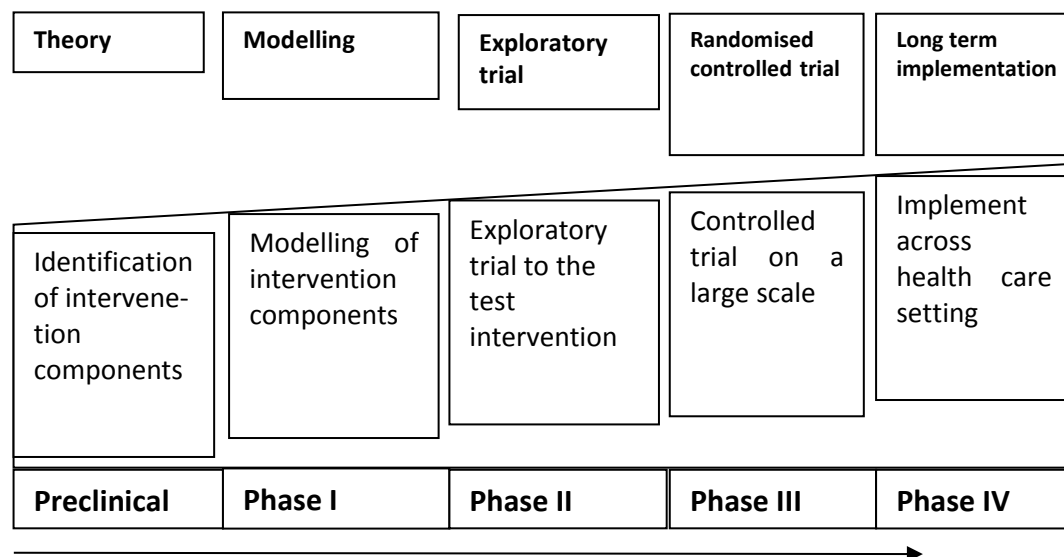
base for non-pharmacological interventions, so that these interventions are developed with the same scientific rigour used to develop pharmacological interventions. The guidelines provide a framework for the stages of intervention development, with two important precursors to intervention design: to select a theory on which to base the intervention and to plan an evaluation at the design stage (Campbell et al, 2000; Craig et al, 2008). The guidelines for evaluation are that each separate component of the intervention should be evaluated independently to determine its own individual effectiveness and whether it is practical and feasible to implement. This section will give a detailed description of the MRC's guidelines and discuss how they were used in this research.

An intervention that is composed of several interacting components would be considered a complex intervention (Campbell, 2007). According to the MRC's guidelines, complex interventions are required when there are many different factors which influence the target behaviour (e.g. adherence to medication) and large variability in outcomes (Campbell et al, 2000; 2007). Adherence interventions can also be considered to be complex because the target behaviour (adherence to medication) is difficult to change and to sustain. Further a behaviour change intervention focussing on altering psychological constructs (e.g. beliefs and emotions) is complex because of the large number of different variables involved. The measurement of these psychological constructs provides a study with many outcome variables to be measured. It has been suggested that there are 'specific difficulties in defining, developing, documenting and reproducing complex interventions that are subject to more variation than a drug' (Campbell, 2000, p694).

The MRC's framework explains that trials for interventions should include various phases in their development from preclinical to implementation of an intervention across the NHS. The aim of carrying out the preclinical phase is to identify theory and potential intervention components through literature reviews and exploratory studies. Phase I involves modelling the potential components, by looking at their relationship with the target behaviour. Phase II is informed by the former phases and is an exploratory trial of a behaviour change intervention. Phase III is a randomised

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controlled trial (RCT) and Phase IV is large scale implementation of the intervention across the healthcare service.



Continuum of increasing evidence

Figure 5. MRC's framework for the design and evaluation of complex interventions (Campbell et al, 2000)

Before large scale RCTs are developed to change behaviour, there needs to be preliminary work to ensure that the intervention has a high likelihood of success in changing the target behaviour. While randomised controlled trials (RCTs) are often noted as the gold standard to evaluate an intervention, this does not imply that they should be used for all research projects (Campbell et al, 2000). RCTs are expensive and labour intensive and should not be embarked upon unless there is good evidence to suggest that they will be a success and worthwhile. The continuum of increasing evidence (see Figure 5) is recommended because it allows interventions to be designed with background work and reasonable expectation that they will be effective. An RCT is therefore one of the final phases in the development of an intervention. When little is known about the theory underpinning a given intervention, it is important to carry out research in the early phases of the MRC's guidelines, e.g. theory, modelling and exploratory trial. The work presented in this thesis used the MRC's guidelines for the

early phases of intervention development, see Table 2 for the research undertaken at each stage.

4.3 Theory Selection; Extended SRM and EPPM

In summary of the theories selected, this research has drawn on two complementary theories of behaviour; the extended self-regulation model (SRM) and the extended parallel process model (EPPM). Both models have been previously used to inform the design of behaviour change interventions (as discussed in the former chapter). Yet each model describes a different mechanism through which to influence behaviour, the extended SRM addresses a patient's view of their illness and medication and the EPPM addresses perceptions of risk and motivation. The selection of these theories will be justified below.

The SRM focuses on representations of the illness as a whole, rather than simply focusing on the health related behaviour that needs to change or be adopted. The extended self-regulation model (extended SRM) is of close relevance to the problem of low adherence to medication, given that it explains how an individual copes with an illness. It describes the psychological (cognitive and emotional) processes which occur when an individual is diagnosed with an illness. The extended model includes the role of medication beliefs as a factor influencing adherence and suggests that if a person has high concern beliefs and a belief that the medication is not necessary, they are less likely to take their medication (Horne, 1997). The authors of the original SRM recognise that responses to an illness are not static and are likely to change over time with increasing knowledge and experience, which is relevant to a condition such as osteoporosis (Leventhal et al, 1984). When an individual has an illness for a long time, it is possible that they gradually gain a deeper understanding of it, which may influence how they manage it. The application of this theory to the problem of low adherence may give rise to a more detailed understanding of how people with osteoporosis make sense of their condition and medication.

The EPPM is similar to the extended SRM in so far as it describes how an individual responds to a health threat. There are two theorised methods of coping with the

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threat; danger control and fear control. In addition, the author of the EPPM provides a theory to explain when a health message (fear appeal) is likely to be successful in motivating individuals to change their behaviour (Witte, 1992). The theory provides advice for how to make a health communication message persuasive by altering risk perception. The model shows that to increase protection motivation, a health message which increases threat (perceived susceptibility, perceived severity) and coping (perceived self-efficacy and response-efficacy) should be used.

The two similar models stand out from other social cognition models. As well as explaining the role of cognitions, they offer an explanation of how an individual's emotional responses to an illness may impact how they choose to manage their medical condition. Both models focus on how a patient will respond to health risk information or an illness diagnosis. The authors of these models theorise that when fear control or emotion focused coping take place, an individual is likely to avoid taking the necessary steps to manage their illness, because their energy is expended on managing/avoiding the emotional response to the information/diagnosis.

The EPPM can make some important additions to the extended SRM, by providing a model for how risk communication should be framed in order to be persuasive. Further, the EPPM highlights the role of efficacy messages to increase the likelihood of behaviour change. The EPPM includes information about how motivation can promote health related behaviours. Similarly, the extended SRM can make some useful additions to the EPPM, by providing an explanation of how patients view and cope with their illness, including specific illness and medication beliefs and emotions which may influence adherence. A further reason the extended SRM is suited to investigate the problem of low adherence is the recognition of behaviour as dynamic in nature, with the inclusion of a feedback loop. This is relevant to a long-term condition such as osteoporosis, because the feedback loop allows for long-term processing of information related to the condition.

The use of two models will ensure many of the variables which have previously been demonstrated to contribute to adherence to medication can be systematically tested,

as well as some variables which have not been previously investigated. This should increase the likelihood of developing effective behaviour change interventions. Using these two models together might produce a strong, comprehensive theoretical framework of adherence to medication. Using one without the other could omit important factors related to adherence. Using these theoretical frameworks would mean that patients' illness perceptions, medication beliefs, risk perceptions and emotional responses could be assessed to determine their problematic beliefs and hence the type of behaviour change intervention that is required. Using these theories allows the identification of specific beliefs which require intervention. Hence this use of theory could add an element of tailoring to the interventions, which has been demonstrated as a successful component in previous interventions (Haynes et al, 2008).

4.4 Research outline

The overall objective of the present research was to design and evaluate a theory-based behaviour change intervention to increase osteoporosis medication adherence, for patients who had difficulties with taking their prescribed medication. To meet this objective, it was decided to find out as much as possible in relation to osteoporosis patients medication adherence, through a series of intervention development studies. The overall purpose of the studies carried out prior to the intervention was to guide the design of the intervention. Each intervention development study has its own objectives, which are briefly outlined below.

This section will also provide the details of how the MRC's guidelines for the design and evaluation of complex interventions have been applied to the research presented in this thesis. A summary of the research undertaken at each stage of intervention development is provided in Table 2. As well as the MRC's guidelines, each of the intervention development studies used the extended SRM and the EPPM to inform their design (see Figure 6 and Figure 7).

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Table 2. Overview of thesis research in relation to MRC framework stages

Intervention development stage (from MRC framework)	Type of study	Title of study
Preclinical	Critical review	Study 1: The psychological factors in non-adherence and non-persistence with osteoporosis medication; a critical review
Preclinical	Qualitative interview study	Study 2: How do osteoporosis patients perceive their condition and medication?
Phase I	Cross-sectional, questionnaire study	Study 3: The psychological factors related to osteoporosis medication adherence
Phase I	Cross-sectional, questionnaire study	Study 4: Osteoporosis patients' ratings of five visual images of osteoporosis
Phase II	Intervention, a series of case studies	Study 5: A multifaceted intervention to increase adherence to osteoporosis medication: a case-series approach
Phase II	Qualitative interview study	Study 6: Process evaluation of a complex behaviour change intervention to increase adherence to osteoporosis medication

4.4.1 Study 1 (Critical Review; Preclinical)

To gain a detailed understanding of what we already know, a critical review of research investigating the relationship between psychological factors (e.g. beliefs & emotions) and adherence to osteoporosis medication was carried out. The included studies were synthesised to produce a list of the known psychological factors that are related to

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osteoporosis medication adherence and persistence. As well as the identification of psychological factors related to adherence, a further objective of this review was to identify gaps in the literature.

4.4.2 Study 2 (Qualitative Study; Preclinical)

The next stage of preparation for the intervention development was a qualitative study to explore in-depth the relevance of the two theories identified in the literature review in chapter 3; the extended SRM and the EPPM. The study investigated how patients think and feel about their condition, medication and the associated fracture risk. A further aim of the study was to explore the content of patients' drawn images of osteoporosis; a method which was used to gain further insight into how patients viewed their condition. The extended SRM and the EPPM were used to guide the interview schedule design. The study objectives were to identify patients';

1. Perceptions of osteoporosis
2. Beliefs about their medication
3. Judgements about their fracture risk
4. Emotional responses to their condition
5. Visual representations of osteoporosis

4.4.3 Study 3 (Quantitative Study; Phase I)

The overall objective of study 3 was to quantify the relationship between psychological factors and adherence, for a theoretical underpinning of the adherence intervention. The psychological factors which were selected for investigation were those of the extended SRM and EPPM, with questionnaires to collect data. Quantitative methods were used to investigate the same factors in study 2. Following this, analysis of relationships between each of these variables was carried out. The objectives were to investigate:

- The extent of self-reported non-adherence to medication in patients with osteoporosis/osteopaenia

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- The range of illness perceptions, medication beliefs, emotional responses and risk perceptions
- The barriers to taking osteoporosis medication
- The factors that are associated with adherence to osteoporosis medication

The psychological factors identified as related to medication adherence were the focus of an intervention to increase adherence to osteoporosis medication. The aims for the intervention are outlined in the study 5 section.

4.4.4 Study 4 (Quantitative Study: Phase I)

The aim of study 4 was to test some potential intervention materials. There is a lack of research of how osteoporosis patients respond to visual images of their condition. Osteoporosis patients were given some images/pictures of osteoporosis to observe and comment on in a questionnaire study, to assess the visual impact. Based upon the premise of the EPPM that threat messages should also include an efficacy message in order to change behaviour (Witte, 1992), each image included an attached caption with an aim to promote self-efficacy. Participants were asked to rate these images and captions in terms of whether they made them feel frightened, informed, angry, motivated, depressed, confident, worried or that there was no point in taking action to improve osteoporosis. The objectives were to explore the following:

- How do osteoporosis patients respond to visual images of osteoporosis?
- Are there a range of responses to various images of osteoporosis?

4.4.5 Study 5 (Intervention Study; Phase II)

The main aim was to pilot a novel multi-faceted adherence intervention to increase adherence to prescribed medication for osteoporosis. This was carried out with eight women with osteoporosis with an N-of-1 case-series design. The adherence intervention was based upon the findings of the previously described intervention development studies and two behaviour change theories; the extended SRM and the EPPM. The intervention comprised: psychoeducation, motivational interviewing

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components and implementation intentions (or plan-setting). An objective of this study was to develop a method for diagnosing patients informational needs in order to develop a tailored intervention. Further aims were to investigate:

- The effect of the intervention on adherence
- The effect of the intervention components on illness perceptions, emotional responses, medication beliefs and risk perceptions
- How patients depict their condition before and after the intervention
- The effective intervention components

4.4.6 Study 6 (Process evaluation study; Phase II)

The purpose of study 6 was to provide a detailed process evaluation of the effectiveness and acceptability of the intervention in study 5. This is a vital step in order to determine whether the intervention could be beneficial if rolled out on a larger scale. Based upon the findings of this detailed evaluation, the intervention could be refined and tested in future research. The follow questions were explored:

- What were the perceived mechanisms of the changes observed in adherence and/or psychological factors?
- What was each participant's subjective experience of taking part in the adherence intervention research?
- Were participants satisfied with the intervention?

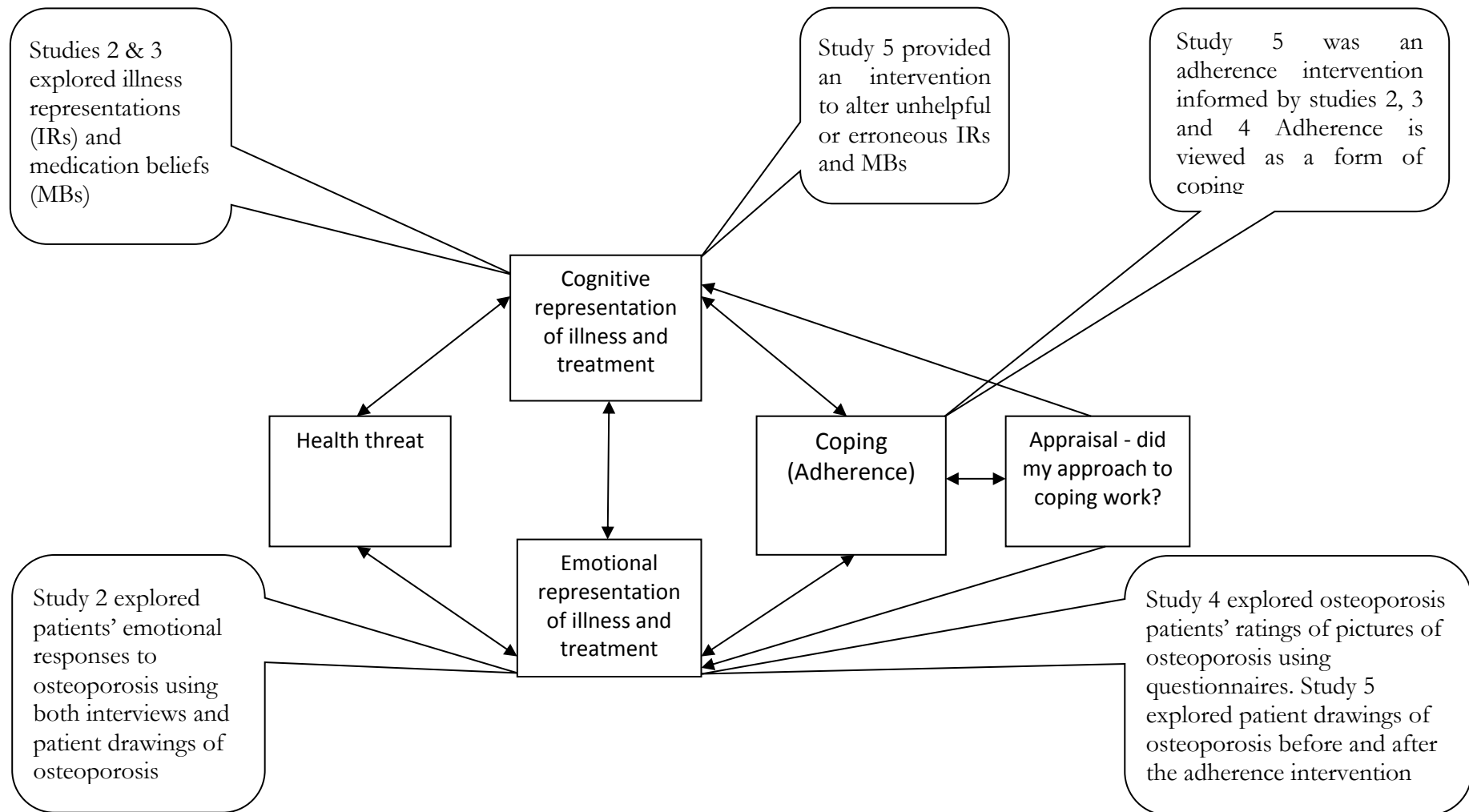


Figure 6. Extended Self-regulation Model annotated for utilisation in the present research

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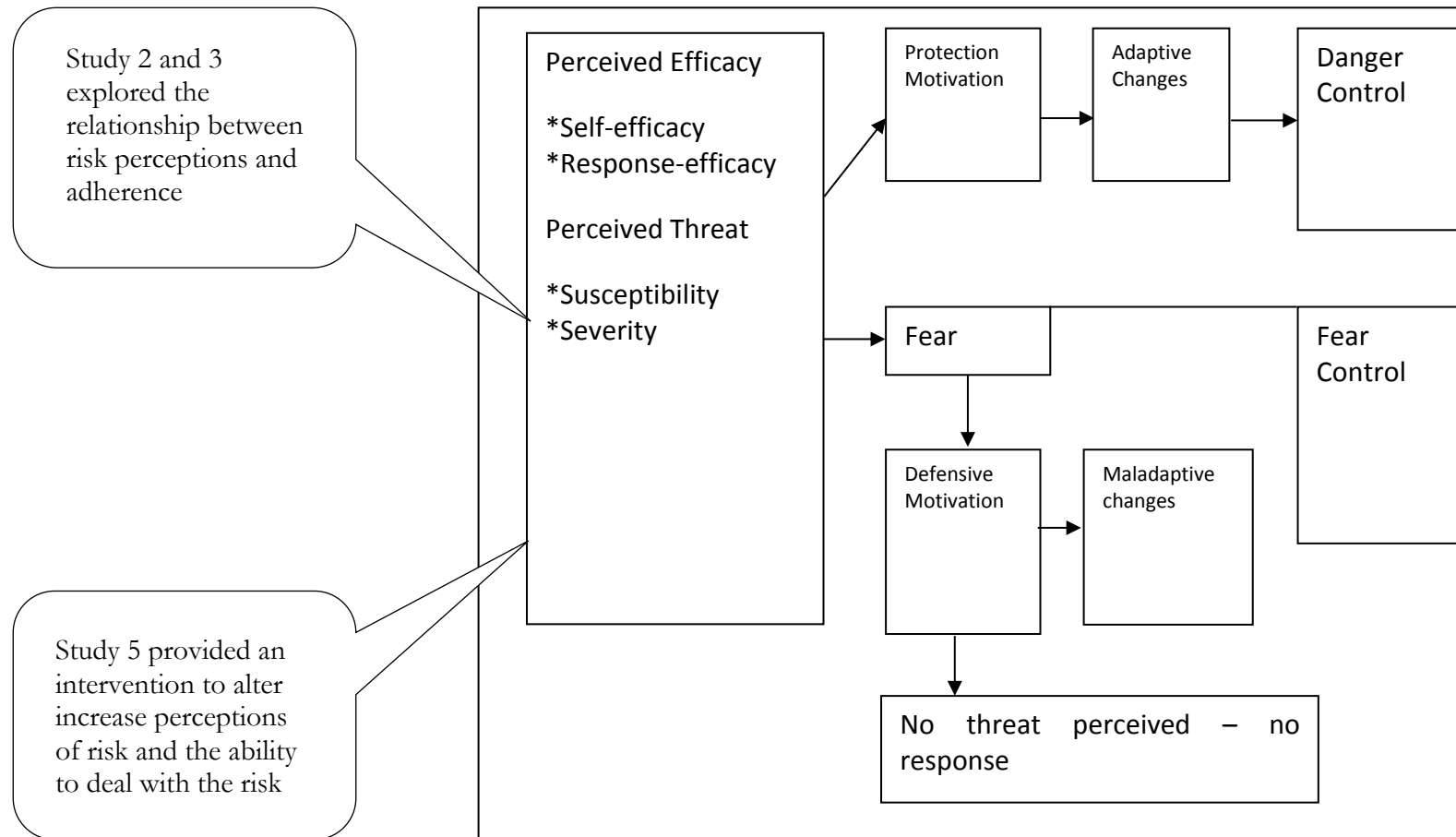


Figure 7. Extended parallel process model, annotated for utilisation in the present research

4.5 Summary

The need for interventions to promote medication adherence is clear, to improve health outcomes for patients and to reduce the healthcare costs involved. However, the most effective method of doing this has not yet been determined. This chapter summarised the theory selection for the present research, in which two theories were combined to investigate the problem of low adherence to medication; the extended SRM and the EPPM. While both theories are similar, a combination allows the exploration of more variables which might be related to adherence.

Two theories have been selected because they can both add something beneficial. The EPPM adds information about the role of motivation, self-efficacy and how to shape/deliver a health risk message. The extended SRM determines the specific beliefs about illness and medication which may require intervention, as well as showing the dynamic nature of an individual's lay model of their illness and how this model continuously adapts to new information.

A psychological intervention which improves adherence to osteoporosis medication could be used in future practice within the NHS to improve the quality of osteoporosis care by helping patients to get the most health benefit possible from their medication, or adapted for use with patients with other medical conditions. This could have implications for future policy making. This thesis will proceed to present a series of intervention development studies. The first stage of intervention development was a systematic search of the literature and synthesis of studies which focused on the psychological factors associated with adherence and persistence with osteoporosis medication.

5 Study 1: The psychological factors in non-adherence and non-persistence with osteoporosis medication; a critical review

Chapter overview

Before designing an intervention to promote medication adherence, it is essential to identify the psychological factors and theories which are related to the target behaviour. Literature focusing on the psychological factors related to adherence and persistence with osteoporosis medication was critically reviewed. Online databases were searched and 13 articles met the inclusion criteria for the systematic review. The papers were assessed for quality. Data from studies which were rated as being of 'high quality' were synthesized to provide a list of the psychological factors associated with adherence and persistence with oral medication for osteoporosis.

5.1 Introduction

Until recently, the psychological factors/drivers of non-adherence to osteoporosis medication had not been investigated. In recent years there has been a new focus on behaviour change interventions that seek to alter psychological factors, based on the premise that behaviour is commonly associated with underlying psychological factors, such as beliefs. Before interventions are designed to promote medication adherence, there is a need to gain an understanding of the psychological factors that underpin adherence to medication (Horne et al, 2005). There is a need to draw comparisons and look for patterns that may exist in the research previously carried out, to identify the psychological factors related to medication adherence.

Much previous work in this area focused on the socio-demographic or clinical factors which are related to medication adherence. While this is fruitful in enabling the identification of patients who may be at high risk of non-adherence, there is no scope for altering socio-demographic or clinical factors. Numerous studies show that various psychological factors are associated with treatment adherence across a range of medical conditions (Horne, 1999; Weinman & Petrie, 2003). In order to carry out a review of the psychological factors related to adherence, it is important to define

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psychological factors. For the purpose of this review, psychological factors are defined as any psychological construct (e.g. belief, emotion or state) which can influence behaviour.

Beliefs about illness and medication have been found to predict treatment adherence in a variety of chronic conditions (Weinman & Petrie 1997; Schousboe, 2013). There is some evidence that this is true for osteoporosis patients. For example, researchers have found the following beliefs to be significantly correlated with adherence to osteoporosis medication: the perceived need for and the efficacy of medication; concerns about medication and side effects (McHorney et al, 2007; Carr et al, 2006; Blouin et al, 2008; Schousboe et al, 2010). In other words, it has been established that an individual's beliefs correspond with their behaviour. This association is important because beliefs about illness and medication are amenable to psychological intervention (Horne et al, 2005). Therefore psychological interventions aimed at changing beliefs may have the potential to impact upon behaviour.

McHorney et al (2007) carried out a study to investigate the drivers of non-adherence to bisphosphonates in osteoporosis patients. It was found that patients who doubted the efficacy and safety of the medication had the poorest adherence (though this was measured by self-report). McHorney et al (2008) have suggested that this shows the need to address patients' medication beliefs and side effects when designing psychological interventions. This is known as the necessity/concerns framework (Horne, 1997). There are many studies across medical conditions to suggest that patients' concerns about their prescribed medication are factors in determining whether they will take their medication (e.g. Horne et al, 1999). For example, in osteoporosis the following concerns about medication have been documented: direct harm, artificiality of medication, lack of understanding in relation to how they work and physician over-prescription of medication (Unson et al, 2003). Further, Schousboe et al (2010) investigated how necessity and concern beliefs influence adherence to medication. They found that doubts about the necessity of medication-taking and concerns about the medication were significantly associated with persistence but not

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adherence to medication. They conclude that there is a different set of drivers of both adherence and persistence.

There is also evidence that the underlying model of osteoporosis and its associated risks that many patients hold is faulty. Giangregorio et al (2008; 2009) investigated fracture patients' causal attributions for fractures. It was found that over half of the study participants believed the cause of their fracture was due to events like a fall rather than to osteoporosis. Not recognising the cause of their fracture to be an underlying bone disease highlights a lack of understanding of the nature of the disease and the cause of osteoporotic fractures. This clearly shows that patients do not understand the risks of their underlying bone condition. These findings are valuable for healthcare professionals and they demonstrate that patients need a clearer understanding of their medical condition if they are going to be able to self-manage it effectively. This is suggestive of the need for a more in-depth investigation of the illness beliefs of osteoporosis patients.

Many studies have explored whether adherence improves when the dosing frequency of osteoporosis medication is reduced. A critical review of these studies indicates a significant improvement in adherence with weekly rather than daily doses of bisphosphonates (Lee et al, 2011). While there is evidence to suggest that less frequent dosing regimens are associated with increased adherence, the authors suggest that psychological factors such as perceived medication efficacy and side effects were as important, if not more so, than dosing frequency when predicting osteoporosis medication adherence.

Much of the previous research surrounding illness and medication beliefs of osteoporosis patients has taken place in the United States and has investigated patients' beliefs about using HRT as a treatment for osteoporosis (e.g. Ballard, 2002). However, given that HRT is no longer a commonly used therapy for the treatment of osteoporosis, papers investigating treatment adherence to hormone replacement therapy were excluded from the present review.

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To give this review a narrow focus, papers reviewing adherence to the following were also excluded; calcium or vitamin D only, infusions to treat osteoporosis, comparisons of daily and weekly doses. The following study types were also excluded: studies of non-psychological factors (e.g. demographic and clinical factors), qualitative studies and studies that used an interventional approach.

Side effects are commonly demonstrated to influence adherence to osteoporosis medication (Carr et al, 2006; McHorney et al, 2007; Penning-van Beest et al, 2008). It is debatable as to whether side effects should be included in a review of the psychological factors contributing to adherence to medication, however, it was decided that side effects would be included on the basis that the interpretation of the experience of side effects is a psychological process (Rief et al, 2011).

The objective of this review was to systematically identify and synthesize existing knowledge about the relationship between psychological factors and medication adherence. The identification of the psychological factors associated with adherence to medication in osteoporosis is beneficial because these factors could be the focus of a future intervention to promote adherence.

5.2 Method

Search Strategy

Variations of the following terms were used to systematically search the databases: osteoporosis, adherence, determinants and medication. A detailed list of the search terms and their variations is included in APPENDIX 1. Endnote was used to discard duplicates (papers which were retrieved on two or more databases). It was decided to search no further databases when saturation point was reached; this was when the final database searched (Medline®) yielded no new papers.

A range of databases were searched, including:

- EMBASE (1974-2013)
- Medline® (1946-2013)

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- PsychInfo (1806-2013)
- Scopus (1945-2013)
- Web of Knowledge (1900-2013)

In addition, the references of all the relevant papers were searched to ascertain whether any papers were not retrieved during the electronic search.

Inclusion Criteria

- Adherence to medication in patients with osteoporosis or osteopaenia
- Oral medications (bisphosphonates, strontium ranelate or raloxifene)
- Measure of adherence to medication and psychological factors
- Quantitative studies assessing the level of significance of any relationships
- All papers published until July 2013 were included

Exclusion Criteria

- Adherence in medical conditions other than osteoporosis/osteopaenia
- Intravenous medications for osteoporosis (e.g. pamidronate, zoledronate or teriparatide)
- Hormone replacement therapy
- Qualitative studies
- Interventional studies to promote adherence
- Studies of the relationship between adherence and demographic/clinical factors

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- Papers were excluded when they investigated adherence to medication for various chronic medical conditions and they did not provide separate analyses for osteoporosis patients' data.

Procedure

The electronic databases listed above were searched using the search terms shown in APPENDIX 1. The titles and abstracts of all the electronic search results were screened for inclusion in the review. Papers that appeared to meet the inclusion criteria were screened in full. When papers were screened in full, many were excluded (see Figure 8 for the reasons for exclusion).

The author assessed the quality of all the included papers, by calculating a total score out of 20; a high score indicated high quality. This was carried out using the assessment tool shown in APPENDIX 2 (Kmet et al, 2004). This tool was adapted for use with non-randomised studies, by excluding irrelevant criteria for quality, e.g. randomisation, allocation concealment etc. The sample size was deemed to be adequate if there were more than 10 participants for each variable being investigated.

To assess the validity of the quality checking procedure an independent assessor also assessed over 50% of the papers (n=8) for quality. Both the author and the independent assessor compared scores to check the level of agreement. It was decided to rate papers that scored >17/20, as high quality. Given that this was a critical review, papers that were not rated as high quality were excluded from the data synthesis. This led to the exclusion of three papers from the review. There was a high level of agreement between both researchers regarding the quality scores of each paper (see Table 3).

Table 3. Comparison of quality assessment scores when rated by two researchers

Authors	Quality Score (author)	Quality score (independent assessor)
Berecki-Gisolf et al (2008)	20	20
Carr et al (2006)	20	20
Fitt et al (2001)	20	20
Huas et al (2010)	19	20
Kamatari et al (2007)	16	16
McHorney et al (2007)	20	20
Rossini et al (2006)	14	13
Penning Van Beest et al, (2008)	19	19

The relationship between a large number of different psychological factors and adherence was investigated. In order to synthesise the data, a table including a list of each psychological factor and its reported relationship with adherence is presented in Table 5. A separate table of the psychological factors in osteoporosis medication persistence is also included in Table 6.

5.3 Results

The search strategy revealed 2975 potential papers for inclusion in the review (see Figure 8 on the next page). When duplicates and irrelevant papers that did not meet the inclusion criteria were excluded, 74 papers remained and were accessed in full text to be screened. This section provides a summary of the papers which were eligible for inclusion.

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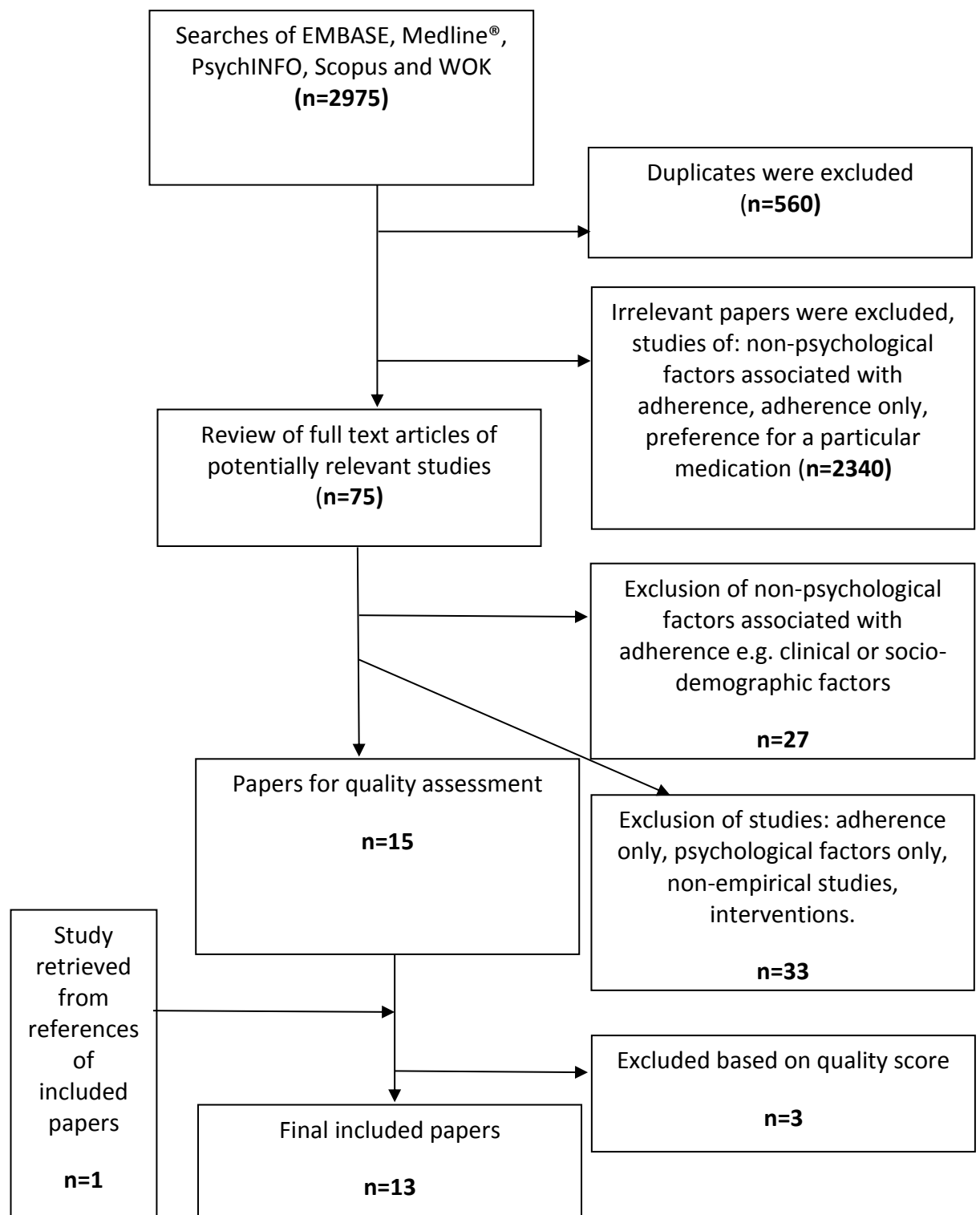


Figure 8. Flowchart of study inclusion/exclusion

Table 4. Summary of studies investigating the psychological factors related to adherence

Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
Berecki-Gisolf et al, (2008)	788	Pharmacy claims	To identify patient and medication factors associated with adherence to osteoporosis medication	Quality of life, mental health, use of antacids lifestyle factors;	Persistence	MPR	Bisphosphonates	Use of antacids and smoking were associated with low persistence. High levels of physical activity were associated with high levels of persistence.	20
Carr et al (2006)*	533	National cross-sectional questionnaire study	To determine the factors associated with adherence and persistence	Concerns about medication, satisfaction with medication, side effects	Adherence and Persistence	Self-report	Bisphosphonates	Side effects and concerns about osteoporosis therapy significantly predicted non-persistence.	20

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
			to bisphosphonates						
Fitt et al (2001)	335	Prospective study using face-to-face and telephone interviews	To determine how bone densitometry influences medication adherence	Patients understanding of their bone scan results, discussion of bone scan results with physician	Initiation	Self-report	Hormone Replacement Therapy (HRT) and bisphosphonates	Women were more likely to initiate their medication if they believed they had a low BMD score rather than a high or normal one and if they had discussed their bone scan with their physician	20
Huas et al (2010)	785	Cross-sectional, observational study	To evaluate the factors influencing non-compliance	Attitudes, knowledge, medication satisfaction and quality of	Compliance	Self-report	Bisphosphonates, SERMs and strontium ranelate	Higher adherence was associated with, high perceived health consequences of osteoporosis, good knowledge	19

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
				life				about osteoporosis and as well participation in exercise and a good mental quality of life.	
Kamatari et al (2007)*	1274	Retrospective questionnaire study	To determine the causes of non-compliance	Adverse effects (AEs), understanding of the disease and satisfaction of explanation by the doctor or pharmacist.	Compliance	MPR	Alendronate and risedronate	Higher adherence was likely with: low report of AEs, ease of to visit the medical facility and the pharmacy and high understanding of the disease	16
McHorney et al (2007)*	1092	Retrospective cohort study	To assess the drivers of non-adherence to medication	Beliefs about medication effectiveness and safety, osteoporosis health	Adherence	MPR and self-report	Bisphosphonates	Lower adherence was associated with concerns about medication effectiveness and safety and the	20

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
				concerns and experienced side effects				experience of side effects Adherence was not associated with osteoporosis health concerns	
Penning-van Beest et al (2006)*	2124	Study of pharmacy record data of medication use	To investigate persistence with bisphosphonates	Occurrence of GI events (as measured by the use of medication to prevent side effects)	Persistence	MPR	Bisphosphonates	Lower adherence was more common in patients with a higher number of reported GI events	20
Penning-van Beest et al	8822	Retrospective Cohort Study	To identify predictors of non-compliance	Side effects as measured by use of gastro-protective	Compliance	MPR	Bisphosphonates (daily and weekly)	Lower adherence was more common in patients with a	19

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
(2008)*			with bisphosphonates	agents (GPA)				higher use of GPAs	
Ringe et al (2007)	5198	1 Year prospective, comparative, multicentre, observational study	To assess compliance to osteoporosis medication and risk factors for non-persistence	Knowledge, quality of life and satisfaction with medication	Compliance and Persistence	Self-report	Alendronate risedronate, raloxifene	Low persistence was associated with low knowledge that medication can prevent osteoporosis and low medication satisfaction Increased quality of life was associated with both increased compliance and persistence	20
Rossini et al (2006)*	9851	Nationwide questionnaire study	To compare adherence to various osteoporosis	Drug related side effects, fear of side effects,	Adherence, including both persistence	Self-report	Alendronate, calcium + vitamin D, HRT, clodendronate	Increased use of GPA was associated with increased non-	14

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
			medications To identify reasons for non-adherence	motivation, safety concerns, inconvenient dosing, recognised risk factors for osteoporosis	and compliance		and raloxifene	compliance Increased knowledge of the risk factors for osteoporosis was associated with higher compliance.	
Schousboe et al (2010)	729	Cross-sectional survey and medical record review	To assess correlates of osteoporosis medication non-compliance and non-persistence	Perceived need for medication, concerns regarding medication, medication-use self-efficacy	Non-compliance and non-adherence	Self-report	Alendronate, risedronate, ibandronate	Low perceived necessity for medication and concerns about medication were associated with low persistence. Low perceived medication self-efficacy was associated with low compliance.	20

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
Solomon et al (2011)	142	Prospective questionnaire study	To design a tool which could be used to predict medication non-adherence	Osteoporosis beliefs, medication beliefs (necessity and concern beliefs)	Adherence	Medication Possession Ration (MPR)	Alendronate, ibandronate, risedronate, zoledronate, calcitonin, HRT, raloxifene and teriparatide	The determinants of low adherence were: side effects, lack of agreement that osteoporosis is a concern, low agreement that the number of medicines prescribed is a burden, lack of agreement that fractures can cause disability, lack of agreement that medications help her remain active and frequent alcohol use.	17
Tosteson et al (2003)*	956	Cross-sectional, observational, telephone	Identification of factors associated with non-	Side effects, knowledge of BMD results, willingness to	Persistence	Self-report	HRT, bisphosphonates, raloxifene	Low adherence was associated with the experience of side effects, low	20

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
		interviews	persistence	take prescribed medications				knowledge of BMD results and low willingness to take prescribed medications.	
Vytrisalova et al (2008)	200	Cross-sectional, questionnaire survey	To assess compliance with prescribed osteoporosis medication	Knowledge	Compliance	Self-report	Alendronate, risedronate, raloxifene, calcitonin.	Knowledge of osteoporosis was not associated with compliance	19
Yood et al (2008)	236	Undefined ?Prospective questionnaire study	To assess the influence of knowledge and perceptions on the decision to	Osteoporosis beliefs, medication beliefs (necessity and concern	Initiation	Medication Possession Ration (MPR)	Bisphosphonate, oestrogen, calcitonin, teriparatide or raloxifene	The determinants of treatment initiation were: high satisfaction with doctor-patient communication, high trust in the	20

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Study authors (in alphabetical order)	Sample size	Design	Primary study aim	Psychological factors investigated	Adherence or persistence and measurement type†	Measure of adherence	Medication type	Key findings	Quality score
			start osteoporosis treatment	beliefs)				physician, osteoporosis good knowledge and high concerns about prescription medications	
Ziller et al (2011)*	293	Questionnaire and interview study with retrospective analysis of medical notes Analysis of adherence	To analyse adherence and persistence with raloxifene	Tolerability Motivational Factors	Adherence and Persistence	Self-report and MPR	Raloxifene	High tolerability and motivation were related to high adherence	16

*Papers including the role of side effects as determinants of non-adherence; †Terms used to denote adherence match those adopted by the papers authors.

5.3.1 Data synthesis

Table 5. Table of the determinants of non-adherence to osteoporosis medication

The psychological factors related to non-adherence to osteoporosis medication	The number of studies that investigated this factor	The number of studies reporting a significant relationship between this factor and adherence
Side effects	3	3
Use of additional medication for gastro-intestinal side effects (proxy measure of side effects)	1	1
Beliefs about osteoporosis	2	1
Perceptions of illness severity	3	2
Illness severity	1	1
Knowledge	4	3
Self-rated knowledge	1	1
Medication beliefs (Necessity)	1	0

The psychological factors related to non-adherence to osteoporosis medication	The number of studies that investigated this factor	The number of studies reporting a significant relationship between this factor and adherence
Medication beliefs (Concerns)	5	4
Perceived drug effectiveness	2	2
Satisfaction with medication	1	1
Medication self-efficacy	1	1
Mental quality of life	1	1
Satisfaction with doctor-patient communication	2	1
Trust in the doctor	1	0
Recall of BMD scan result	1	1

Table 6. Table of the psychological factors related to non-persistence with osteoporosis medication

The determinants of non-adherence to osteoporosis medication investigated	The studies that investigated this factor	The studies reporting a significant relationship between this factor and adherence
Side effects	3	3
Use of additional medication for gastro-intestinal side effects (proxy measure of side effects)	2	2
Illness severity	1	1
Knowledge	1	1
Willingness to take prescribed medication	1	1
Medication beliefs (Necessity)	1	1
Medication beliefs (Concerns)	3	3
Perceived drug effectiveness	1	1
Satisfaction with medication	2	1

The determinants of non-adherence to osteoporosis medication investigated	The studies that investigated this factor	The studies reporting a significant relationship between this factor and adherence
Medication self-efficacy	1	1
Quality of life	2	1
Mental health	1	0
Motivation	1	1

Table 7. The relationship between lifestyle factors and adherence and persistence

The factors related to non-adherence/non persistence with osteoporosis medication	The number of studies that investigated this factor	The number of studies that reported a significant relationship between this factor and adherence
Alcohol intake	2	1
Exercise	3	3
Smoking	1	1
Body Mass Index	1	0

5.4 Discussion

For successful osteoporosis medication adherence in order to reduce the risk of fracture, this critical review emphasises the importance of the following factors; the experience of side effects, concerns about medication, knowledge and perceived severity. Much of the previous research in this field focused on the determinants of non-adherence, with fewer focused on the determinants of non-persistence with osteoporosis medication. It is noteworthy that the studies included good sample sizes and overall had a high level of quality. Only papers with a very high quality score (>17/20) were included in the synthesis of information for the present review. The majority of papers conducted only univariate analysis of the predictors of adherence.

Side effects were the most commonly researched determinants of non-adherence, with agreement between all studies that the experience of side effects is related to osteoporosis medication adherence (Tosteson et al, 2003; McHorney et al, 2007; Solomon et al, 2011;) and persistence (Tosteson et al, 2003; McHorney et al, 2007). In other studies, side effects were measured by mean possession ratio (MPR) for medications to reduce acid related side effects or gastro-protective medications (Penning-van Beest et al, 2006; Berecki-Gisolf et al, 2008; Penning-van Beest et al,

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2008;), because these medications are often used to counteract the side effects of osteoporosis medication. However, it is possible that this proxy measure is not valid for the measurement of side effects.

Concerns about medication have been frequently investigated in relation to both adherence and persistence to osteoporosis treatment, with consistent evidence of a strong relationship. Four out of five studies reported a strong association between adherence and concerns about medication (Carr et al, 2006; Yood et al, 2008; Solomon et al, 2011; McHorney et al, 2007). However, Schousboe et al (2010) did not find an association between concerns about osteoporosis medication and adherence, but did find an association between concerns about osteoporosis medication and persistence. The authors of all the studies investigating the relationship between concerns about osteoporosis medication and persistence found a significant association (Carr et al, 2006; McHorney et al, 2007; Schousboe et al, 2010). Hence there is strong evidence that concerns about medication are related to treatment non-adherence/persistence.

Perceived necessity for osteoporosis medication was only assessed in one study included in this review. While it might be expected that it predicts both adherence and persistence, perceived necessity was strongly related to non-persistence, but not non-adherence (Schousboe et al, 2010). The author's explanation for these mixed findings is that there are different explanatory factors for both adherence and persistence.

Four studies assessed patients' knowledge of osteoporosis and investigated whether such knowledge predicted adherence. While three of the studies found that as knowledge increased, adherence increased (Ringe et al, 2007; Yood et al, 2008; Solomon et al, 2011), the other study did not find any association (Vytrisalova et al, 2008). It should be noted that knowledge was measured differently in each study and this could account for the discrepancy between findings. However, overall the majority of evidence suggests that knowledge of osteoporosis is an important determinant of adherence. Further, recall of the bone mineral density scan results was associated with better adherence (Fitt et al, 2001). Perceived knowledge was also related to adherence in the only study it was investigated (Huas et al, 2010). This finding is in agreement

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with Leventhal's SRM, in which it is theorised that when a patient feels that they have a coherent model or understanding of their illness, they are more likely to adopt a problem-focussed coping mechanism, such as adherence.

Patients' perceptions of the severity of the condition have been the focus of three studies, two of which showed an association with adherence (Yood et al, 2008; Huas et al, 2010). One group of researchers found a link between the actual severity of osteoporosis with both adherence and persistence (McHorney et al, 2007). Overall there is evidence to suggest that when patients perceive themselves to be at risk of a fracture, they take their medication as prescribed.

As well as investigating the psychological determinants of adherence, many of the studies included in this review have drawn out a relationship between lifestyle factors (e.g. diet, smoking, exercise) and adherence. In three studies, engagement in physical exercise was associated with increased adherence, however, it is unlikely that lifestyle factors and non-adherence are causally related. A possible explanation for the relationships detected between lifestyle factors and adherence is that a person who is non-adherent also engages in other behaviours which may cause a risk to their health. Perhaps this relationship is due to smokers and non-adherers placing little value on their health.

5.4.1 Gaps in the literature

There has been little exploration of the emotional response to having osteoporosis as a predictor of non-adherence to osteoporosis medication. While two studies investigated a relationship between mental health/ mental quality of life and adherence, there were mixed findings. One study found an association between high adherence and good mental quality of life (Huas et al, 2010), another study found no association between mental health and medication persistence (Berecki-Gisolf et al, 2008). This review has identified a gap in the literature, with the need for more investigation of the role of emotional response to osteoporosis in adherence and persistence with osteoporosis medication. It is theorised that emotional response to a medical condition is likely to influence and be influenced by the behavioural

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response/coping mechanisms (Leventhal et al, 1997): effects may be bi-directional and can only be understood when investigated in prospective or intervention studies.

A further gap in the literature is only two of the included studies investigated the relationship between adherence and motivation (Tosteson et al, 2003; Ziller et al, 2011). Further, medication self-efficacy was only investigated in one study, with a reported relationship between this factor and both adherence and persistence. Overall this is a gap in the literature worthy of more research, because motivation is a factor for which psychological interventions are available.

Apart from the necessity/concerns framework (Horne et al, 1997), no researchers explicitly used other health psychology theories to guide their exploration of the psychological determinants of adherence and persistence with osteoporosis medication. This sheds light on a problem with the research in this area to date, because lack of theory-base means that important determinants of behaviour may be omitted from the investigation. A lack of theory-base also means that mediating processes/mechanisms cannot be explored. Future research could provide more insight to the problem of low adherence if the determinants are explored using a theoretical focus.

This review indicates that there are very a small number of studies which investigated the relationship between beliefs about osteoporosis and adherence to osteoporosis medication, with two sets of authors reporting studies of the relationship between beliefs about osteoporosis and adherence. One group of authors reported a relationship between adherence and beliefs about osteoporosis, whereas another group of authors did not (Solomon et al, 2011). There was a tendency for previous researchers to investigate perceptions of osteoporosis using healthy participants, rather than a clinical population of osteoporosis sufferers (Hsieh, 2001; Ballard, 2002; Williams et al, 2002; Gerend, 2006). However, there is a need for more studies to assess the relationship between beliefs about osteoporosis and adherence in a clinical population.

5.4.2 Limitations

A major limitation of the studies investigated is the common use of cross-sectional designs to examine the relationship between psychological factors and adherence. Therefore it is difficult to know if factors such as beliefs are causal for adherence or whether they are an effect. This is particularly true for factors such as emotions and quality of life, which may be the end result of a worsening medical condition which is due to low adherence. Also, some of the possible psychological predictors of adherence may be related to each other, such as side effects and concerns about medication. Multivariate statistics are needed to evaluate the contribution of each of the variables to the prediction of adherence.

The present critical review included only published manuscripts, which means it is likely to be influenced by publication bias. It is noteworthy that many studies do not report factors which were not associated with adherence. A review of unpublished work would be beneficial and could enable the discovery of factors unrelated to adherence. Further, a review of qualitative studies investigating the determinants of adherence would also be beneficial and may be able to fill some the gaps in the literature.

Research for each psychological factor was synthesised in Table 5 and Table 6. The problem with synthesizing data of this nature is that often the questionnaires/measures for each psychological construct are not the same. For example, in one study, knowledge was assessed using a 4 item questionnaire (Ringe et al, 2003), whereas in another, knowledge was assessed using a 20 item questionnaire (Vytrisalova et al, 2008). Further the 4 item questionnaire included items of knowledge about medication, whereas the 20 item questionnaire focused on knowledge of osteoporosis only.

A further difficulty was that the various authors used different terms to signify adherence, compliance and persistence. It would be beneficial if the scientific community who study adherence to medication could use the same definitions of adherence, which would allow ease of comparison across the literature.

5.5 Summary and next steps

There is strong evidence from this critical review that if behaviour change interventions are targeted at the following psychological constructs, adherence to osteoporosis could be improved: the experience of side effects, concerns about medication, knowledge and perceived severity of osteoporosis. Other psychological factors require more research to determine their relationship with adherence, such as beliefs about osteoporosis, emotional responses and motivation for adherence. There is a need for theory-based research to investigate the determinants of non-adherence.

Before adherence interventions are designed, it is vital to do preliminary research to investigate the psychological determinants of the target behaviour for the particular patient group/medical condition being investigated. In particular, it would be worthwhile for such studies to be theory-based and to further investigate the relationship between illness beliefs, emotions and risk perceptions and adherence to osteoporosis medication. There are few studies assessing the relationship between the following psychological factors and adherence: medication self-efficacy, perceived necessity for medication, emotional responses and mental health/mental quality of life, which shows the need for further research to determine these relationships.

The next two studies will focus on the gaps in the literature identified in this review. A theory-based investigation of the relationship between psychological factors and adherence will be the focus of a questionnaire study (study 3) presented in chapter 7. However, prior to this, a qualitative study was carried out to explore how osteoporosis patients perceive their condition and medication for it. This qualitative study is presented in the following chapter, with an overall aim to ascertain whether two theories of health behaviour have the potential to be beneficial as a basis for an intervention to improve osteoporosis medication adherence.

6 Study 2: How do osteoporosis patients perceive their condition and medication?²

Chapter overview

The work presented in this chapter constitutes a qualitative research project investigating the illness and treatment perceptions of osteoporosis patients. This study had two key aims: (1) to explore osteoporosis patients' perceptions about their condition and medication; (2) to identify potential cognitive and emotional factors that may be related to osteoporosis medication adherence. In the present study, illness perceptions, medication beliefs, emotional responses and risk perceptions were explored using semi-structured interviews. To gather more data about how patients perceive their condition, they were asked to create a visual representation of osteoporosis through the use of drawing.

6.1 Background

The goal of anti-osteoporosis medication is to reduce fracture risk, improve quality of life and reduce hip fracture associated mortality (Bock & Felsenberg, 2008). Numerous researchers have concluded that osteoporosis medication can reduce the risk of fracture (Cranney et al, 2002; Wells et al, 2008). However, as discussed in chapter 2, osteoporosis patients commonly do not take their medication as prescribed by their doctor. Overall non-adherence renders medication an ineffective intervention. Non-adherence to osteoporosis medication can result in increased risk of fractures and associated hospital admissions (Rabenda et al, 2009). There is a clear need for researchers to develop novel interventions to promote medication adherence, in order to help patients manage their condition effectively.

Illness perceptions and medication beliefs have been found to be related to medication adherence for a variety of chronic conditions (Weinman & Petrie, 1997). Further, risk perceptions have been shown to be important motivators of health

² This paper was published online and was selected for publication in a special issue of the Archives of Osteoporosis (Besser et al, 2012). It was also presented at the British Psychological Society (BPS) Division of Health Psychology (DHP) annual conference (Besser et al, 2011).

protective behaviours and this is also true for osteoporosis medication adherence (Giangregorio 2008; 2009). There have been many qualitative studies to explore patients' perceptions of adherence in other medical conditions (e.g. Dean et al, 2005), as well as qualitative studies of osteoporosis patients medication adherence (e.g. Unson et al, 2003). However, to the author's knowledge there have been no qualitative studies in relation to osteoporosis patients medication adherence based upon a theoretical framework. Given that these psychological factors are likely to underpin adherence behaviour, it was decided that a theory-based qualitative study would be carried out with osteoporosis patients to explore these factors in further detail.

In addition to exploring the cognitions associated with illness through interviews, it may be useful to study how osteoporosis patients visualise their illness, as an alternative way of understanding their perception of their condition. Drawing is becoming a widely used method for exploring how patients view illness (Guillemin, 2004) and can be used in addition to interviews/questionnaires to assess cognitive and emotional representations of illness (Kaptein, 2010). A patients' visual representation of their illness is important and it may hold information which they use to determine how they will manage their illness. To date there has been no published exploration of the visual representations of osteoporosis patients.

6.2 Introduction

A qualitative study, based upon the components of the extended Self-Regulation Model (SRM), could expand current knowledge of how patients with osteoporosis make sense of their illness. A study of this nature could reveal detailed information of how people with osteoporosis view their illness. It is clear that interventions are needed to help patients with osteoporosis adhere to medication regimes. However, prior to intervention design it is important to carry out an exploratory study in order to gain a greater perspective and understanding of the potential theories and surrounding issues influencing an intervention of this nature (Campbell et al, 2007). In

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this case, the exploratory study needs to investigate patients' cognitions and emotions which are likely to be related to medication adherence.

Visual representations (imagery) of illness have been explored in coronary heart disease (Broadbent, 2006a), cancer (Harrow et al, 2008) and headaches (Broadbent, 2009). Exploring visual imagery provides a platform to challenge patient's mental images which may be negative or incorrect (Harrow et al, 2008). There is evidence to suggest that patients do hold mental images/representations of their illness. For example, Broadbent et al (2006a) found images to be useful in demonstrating how patients made sense of myocardial infarction (MI). Patients were asked to draw a picture of their heart after suffering an MI. They found that the size of a patient's drawing of their heart was related to recovery, as measured by the speed at which participants returned to work. Patients who drew bigger hearts were slower to return to work. This shows how patients' visual representations can be related to health outcomes.

Furthermore, there are studies which indicate that using images could be powerful motivators for changing intentions and health behaviours (Shahab et al, 2007, Harrow et al, 2008). These studies are discussed in detail in study 4. If visual images can motivate behaviour change, then it is very important to investigate the way in which patients mentally visualise their illness/potential illness. Therefore the possibility exists, for patients who hold mental images with erroneous concepts of their illness, to modify their behaviour through intervention e.g. education about the illness. It would be beneficial if health care professionals understood the way in which patients view their illness in order to be able to help them to manage it.

There has been a study of breast cancer patients' visual representations of their condition (Harrow et al, 2008). This paper focused on the way in which patients' mental images develop and how these are related to their illness beliefs about cancer. It was found that the participants (women with breast cancer) had very detailed mental images about their cancer and that these were strongly related to their illness beliefs. One of the participants in this study provided an example of how using an

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image can alleviate fears, e.g. her image of cancer changed from that of a snake moving around the body to a cloud which was in one place. This change in her mental representation of the disease made her feel less worried about the condition. The study reports *'analysis suggested that the images offered by health professionals had the potential to remove or ameliorate anxiety or fear'* (Harrow et al, 2008, p 343). This shows how the use of images can be used to improve communication between health care professionals and patients. Furthermore, these authors found that clinicians' use of visual representations of cancer, e.g. showing mammograms during their consultations was influential for altering the patients' mental representation for their illness. This supports the idea that visual stimuli are understood by patients and can be used to alter mental representations.

Cameron (2009) did a study which assessed the association between illness risk representations and risk appraisal, worry, self-protection intentions and self-protection behaviours in patients with skin cancer. Illness risk representations are risk perceptions which are studied in relation to the self-regulation framework. Importantly, concrete visual images were predicted to be more influential than abstract information about the illness when aiming to change behaviour (Cameron, 2009). It was found that the vividness of the patients' symptom imagery independently predicted intentions and skin cancer risk reduction behaviours.

An extension of the SRM was used to guide the design of the interview schedule. This was carried out in conjunction with previous research which suggests that cognitions/emotions about illness and medication may influence adherence to medication in other medical conditions, as well as in osteoporosis (e.g. Carr et al, 2006; McHorney et al, 2007). A study which investigates the way in which patients make sense of their illness using cognitive, emotional and visual representations could provide beneficial information to HCPs. Further, it could offer insight into the patients' perspective of the illness. In turn the provision of such information could allow HCPs to address any common illness misconceptions held by patients.

Rationale for study

While there has been research investigating the role of medication beliefs and risk perceptions in osteoporosis medication adherence, there have been no previous studies investigating the role of illness perceptions from the extended SRM. This study could inform future interventions by helping to define the components required for an intervention of this nature, for example; which erroneous patient cognitive/visual representations require intervention? The psychological factors focused on in this study can be found in Figure 9. The literature indicates that patient's medication beliefs and risk perceptions may also influence their adherence to osteoporosis medication, so these beliefs are being further investigated in this study. Much of the previous research of individual's illness beliefs about osteoporosis has been carried out with healthy participants as opposed to osteoporosis patients. This indicates the need for a study which utilises a clinical population.

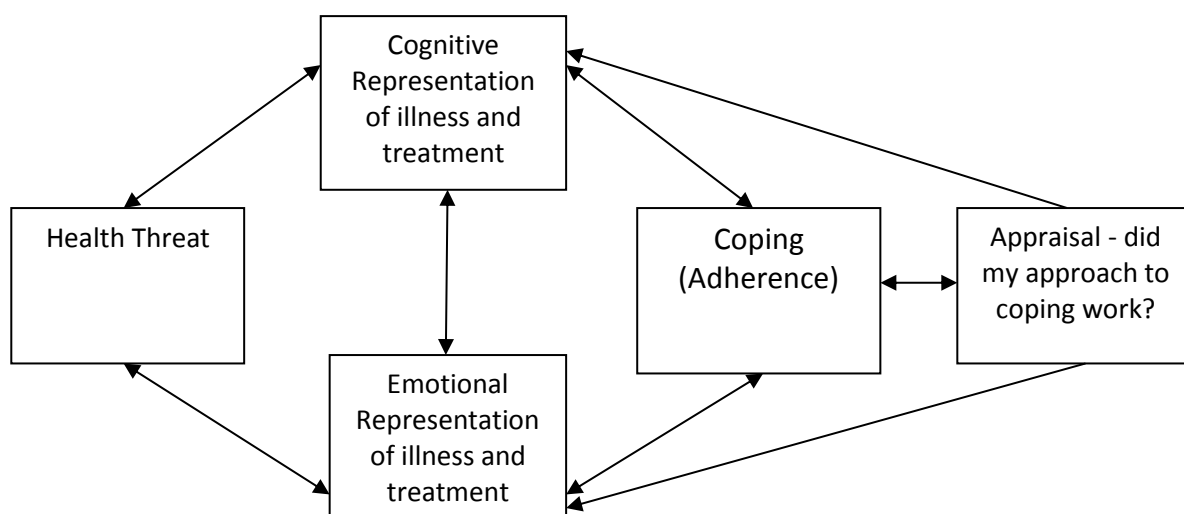


Figure 9. The extended self-regulation model (SRM) (adapted from Leventhal et al, 1984).

6.3 Aims

The overall aim of this study was to explore how osteoporosis patients think and feel about their condition and its treatment. The study explored how patients make sense of their illness and the associated fracture risk. The content of patients' visual representation of osteoporosis was also explored. The objectives were to identify patients'; perceptions of their illness, beliefs about their medication, emotional responses to osteoporosis, judgements about their fracture risk and image

representations of osteoporosis. A further aim was to explore the psychological factors which might be related to adherence to medication, which might inform the design of an intervention to improve adherence.

6.4 Method

6.4.1 Study Design

Semi-structured face-to-face interviews were used to gather information from hospital outpatients with osteoporosis. A qualitative methodology was chosen for this study because there is little previous work exploring the illness perceptions of osteoporosis patients (none of which utilised the SRM). Qualitative research enables the in-depth investigation of participants' views and experience. This is the preferred research methodology for studies aiming to explore peoples' attitudes and motivations (Keats, 2000).

The interview schedule covered the following topics: illness perceptions (identity, timeline, causes, controllability and consequences); emotions about the condition, medication beliefs (perceived need for medication and concerns about medication); risk perceptions (perceived severity and susceptibility) and adherence to medication. In addition to the interviews, patients were asked to draw a pair of bones, one with osteoporosis and one without. Half of the participants were also asked to draw a pair of people, one with and one without osteoporosis. Participants were asked to draw at the beginning of the interview, at the point when they were asked questions about the nature of the osteoporosis.

Interview schedule development

Patients and service users were involved in the design of the study. A focus group was conducted by the researcher in which service users were asked "what questions could osteoporosis patients be asked to gain a more in-depth understanding of how they see their illness." This question was written on a large piece of paper and the service users were given post-it notes, on which they were asked to make a note of potential questions. The author also took part in this activity. Once the questions were formulated, the author and service users put them into categories and placed them in

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a logical order for interview. The service users generated some useful questions, such as ‘how does having osteoporosis influence your daily life? The interview schedule can be found in APPENDIX 5.

The extended SRM model was used as a guide to generate additional questions to capture key theoretical constructs. This helped to formulate additional questions focussing on osteoporosis patients: illness perceptions, medication beliefs, emotional responses and risk perceptions, as well as adherence to medication. Finally, an expert patient reviewed the complete interview schedule and piloted the drawing task. She was asked to comment on the questions in terms of how easy they were to understand and whether the wording was appropriate. The expert patient was able to provide advice on questions which were not clear. She also drew a bone of an individual with and without osteoporosis. While she was apprehensive about the task, she reported that it posed no major difficulty.

6.4.2 Participants

Fourteen female outpatients with osteoporosis (n=10) and osteopaenia (n=4) took part in the study (mean age 69; range 58-82; SD 10.1). All participants had been prescribed medication for osteoporosis in the past or present, though one was in the process of deciding whether or not to start taking it. The number of fractures suffered ranged from zero and eight throughout their lifespan. They had suffered with osteoporosis for between two and 30 years prior to the interview. The majority were retired from work (n=9/14). Participant demographic and clinical information is summarised in Table 8.

Table 8. Study 2 participant's demographic and clinical Information

ID	Age	Diagnosis	Occupation	Number of Fractures	Number of years with osteoporosis/ osteopaenia
1	62	Osteoporosis	Nurse	0	2
2	82	Osteoporosis	Retired	3	6
3	60	Osteoporosis	Lecturer	6	5
					130

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ID	Age	Diagnosis	Occupation	Number of Fractures	Number of years with osteoporosis/osteopaenia
4	76	Osteopaenia	Teacher (retired)	5	3
5	72	Osteoporosis	Office Worker (retired)	3	15
6	82	Osteoporosis	Lab Technician (Retired)	Unknown	Unknown
7	56	Osteopaenia	Government Officer	1	3
8	64	Osteoporosis	Manager (Retired)	8	10
9	80	Osteoporosis	Artist	8	10
10	80	Osteoporosis	Office Worker (Retired)	Unknown	Unknown
11	59	Osteoporosis	Unemployed	0	3.5
12	58	Osteopaenia	Teacher (Retired)	0	Unknown
13	62	Osteopaenia	Teacher (Retired)	0	5
14	79	Osteoporosis	Sales Worker (Retired)	5	30

The participants were recruited from two clinics: a) an osteoporosis clinic screening research unit and b) a rheumatology clinic at a London teaching hospital and included patients who attended all their hospital appointments and patients who did not attend (DNA) their last clinic appointment. DNA is defined as a patient who did not attend their last clinic appointment with their doctor and did not contact the clinic to inform staff of the cancellation. DNA patients were included on the premise that as they are non-adherent to appointments, then they may also be non-adherent to medication and thus could provide insights into factors related to non-adherence. Eight of the women attended their last clinic appointment and six did not. Participants who did not speak English had to be excluded because this is a student project, with no available funding for translators.

The majority of study participants had previously taken part in a clinical trial to measure the effects of teriparatide (an anabolic anti-osteoporosis agent described in chapter 1) on bone mineral density. Hence this was a group of patients who were likely

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to have been quite well informed about osteoporosis and medication. The clinical trial involved taking regular measurements of bone mineral density; therefore participants were given feedback about their condition regularly, which is unusual for osteoporosis patients.

6.4.3 Procedure

Ethics

Ethical approval was sought from the proportionate review sub-committee of the South West London Research Ethics Committee (REC) 3 who gave a favourable opinion. Once a favourable opinion letter was received from the REC, research and development (R & D) approval was also obtained from Guy's and St. Thomas' R & D department. Patients were required to give written consent to take part in the study and for it to be audio recorded. It was arranged that the clinic doctor was available at the time of the interviews in case there were any adverse events.

Recruitment

Using the inclusion/exclusion criteria, a member of the clinic administrative staff identified 45 suitable participants and provided the author with their names and addresses. The author contacted these potential participants by post, 29 of these were non-attenders. A letter of invitation to take part in the study, together with an information sheet and a consent form were sent to the potential participants. They were also given the author's contact details and encouraged to get in contact if they had any questions about the study. Participants were asked to sign and return the consent form if they agreed to take part. It was made clear to the participants that participation is voluntary and their hospital care would not be affected in any way whether they chose to take part or not. Participants were offered £5 for taking part, to cover the cost of expenses. Due to participants being recruited by post for this study, it is not known why some patients decided to decline their invitation. The inclusion criteria were: a diagnosis of osteoporosis or osteopaenia, experience of taking oral medication for osteoporosis (e.g. alendronate or strontium ranelate), willing to take part in an interview and English speaking.

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Interviews took place between September and November 2010. Interviews were carried out in a private room on the osteoporosis unit at Guy's Hospital, London. The choice to carry out the interviews in the hospital was so that clinic staff would be there to provide advice and support if an interviewee became upset or unwell. The duration of the interviews was between 30 and 90 minutes in total. The clinic doctor introduced each participant to the author, who proceeded to explain that the research was being carried out for educational purposes. Each participant was given an overview of the topics included in the interview, which were: a section about osteoporosis, a section focussing on medication and finally a drawing exercise. It was highlighted that the interview was not a test, there were no right or wrong answers and that the interview was concerned with people's personal experience of having osteoporosis.

Each participant was firstly asked questions from the demographic questionnaire. This was carried out at the beginning of the interview in order to put the participant at ease with some easy questions. Following this, the participant was asked questions using the prompts from the interview schedule (see APPENDIX 5). Throughout the interview the researcher checked that the participant's meaning was understood by repeating back their responses in summary form.

Participants were asked to complete 4 drawing tasks. They were first asked to draw a bone without osteoporosis. They were then asked to draw a bone with osteoporosis. They were then asked to draw a person with and without osteoporosis (using 'stick people' for ease). The drawings were then the focus for a discussion about what lay behind the drawings, how they experienced osteoporosis and the effects it had on them. The drawings thus provided a way to approach the emotional aspects of having osteoporosis.

6.5 Analysis

6.5.1 Interview analysis

Interviews were transcribed verbatim by the author. Framework analysis was used to make sense of the data transcripts (Ritchie et al, 2003). Framework analysis focuses on

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keeping the data close to what the participants actually say: therefore it is a useful type of analysis for a study which will be used to inform a future intervention study.

Framework analysis consists of 5 main practical steps. While these steps are described separately it should be noted that they are intertwined and can overlap and occur simultaneously (Ritchie et al, 2003). The main practical steps are familiarisation, thematic analysis, indexing, charting, mapping and interpretation, which are described in relation to this study below.

Familiarisation

The researcher immersed themselves in the data in order to gain an overall picture. This process of familiarisation was carried out by listening to the audio-recordings, transcribing the interviews, then reading and re-reading the transcripts.

Thematic Analysis

Thematic analysis is a method of identifying and recording the major themes that occur in the data (Howitt, 2010). The thematic analysis can be carried out during the familiarisation phase, where a list is made of both the themes introduced by the interviewer and the themes that the participants generate. Once a list of themes was generated it was refined, so that overlapping constructs were combined. This resulted in a list of main themes and sub-themes.

Indexing

Each theme and sub-theme identified during the thematic analysis was given a number and letter code, e.g. main theme were given numbers 1, 2, 3 etc. and sub themes were assigned a, b, c etc. The author read through all the data, recording the relevant theme/subtheme (codes) in the margins of the recorded data. This allowed for themes which were continuously mentioned together to become clear.

Charting

At this stage a chart was developed, consisting of columns of themes and sub-themes, with a row for each participant. Quotes from the transcripts for each theme were transferred to this chart. This allowed all data for each theme and sub-theme to be

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viewed together in one column, to make it easy to compare the responses of different participants about the same topic.

Mapping and Interpretation

This is the final stage in which the final thematic framework of the data was identified. In the mapping stage a new chart was made. For each theme, data were merged into broader categories. These categories were then refined to ensure that they did not overlap. From this new chart the data were ready to be interpreted. This involved examining the data in relation to the original research questions. The new chart map presented data for each theme in a new column. A further column was used for interpreting the data contained in each theme. Relationships between themes were examined, as well as similarities and differences between the two groups (attenders and non-attenders).

Two independent researchers each coded two of the transcripts to check the reliability of the coding framework (see APPENDIX 6). This provided instructions for how to code each theme, which included a description of the themes and examples of quotes typical of such themes. In order to check the accuracy of coding, each transcript was discussed between the researchers in detail. Any discrepancies in coding were discussed until there was consensus in relation to how the coding could be refined and how codes should be interpreted and applied.

6.5.2 Patient drawing analysis

Fourteen participants completed two drawings; one of a bone with osteoporosis and one without. Seven of the 14 participants completed an additional pair of drawings of both a person with osteoporosis and a person without osteoporosis. To investigate what the drawings revealed about patients' illness representations, they were analysed by looking for the major features, focusing on the length, shape and bone deformity depicted. Drawings of bones with and without osteoporosis were measured through their longest line and the results between each participant's pair of drawings were compared. Drawings were categorised for their similarities and differences, both

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within and between participants. The descriptions that participants gave about their emotions associated with the drawings were re-examined alongside their drawings.

In a validity exercise, three researchers were asked to describe their observations of the drawings of individuals with and without osteoporosis. The purpose of this was to investigate any additional features and themes which the author had missed, to compare and validate the researchers' interpretations and to check whether any new themes emerged. There was agreement between researchers in the themes identified, though the researchers identified additional features to those identified in the preliminary analysis, which were old age and infirmity.

The three researchers were also given all of the participants' sketches of bones (a total of 28 drawings) and were asked to put them into pairs of sketches they believed to be drawn by the same participant. To analyse the differences between the pair of bones drawn by each participant, three researchers were asked to filter through a collection of all 14 participants bone sketches which had been separated in to two groups (one group of sketches of bones with osteoporosis and a second group of sketches of bones without osteoporosis). The sketches were anonymous and therefore the participants could not be identified by the researchers. The researchers' task was to go through the collection and match pairs of sketches of bones they believed to have been drawn by the same participant. As well as identifying pairs of bones which were drawn by the same individual, the researchers were asked to identify which sketches were of osteoporotic bones and which were not. The same process was carried out for the seven pairs of drawings of people with and without osteoporosis.

6.6 Results

For the attender group, 16 participants were invited to take part in the study and six did not respond. For the DNA group, 29 participants were invited to participate and 25 did not respond. Thirteen global themes initially emerged from the interview, with 59 themes and 129 sub themes. This was aggregated to 11 global themes, 32 themes and 24 sub themes (see Table 9). To aggregate the themes, all themes were listed and where there were overlapping concepts, the themes were merged. For example;

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medication beliefs was formed from two similar themes: beliefs about medication in general and beliefs about osteoporosis medication.

Table 9. Main themes and sub themes

Global Theme	Themes	Sub-themes
Identity	Knowledge	
	Visual representation	
	Symptoms	
Causes	Causes of osteoporosis	Modifiable and un-modifiable
	Causes of fracture	
Timeline	Chronicity	
	Timeline of medication	
Controllability/Cure	Feeling in control	
	Confusion about control	
	Cure	
Consequences	No direct consequences	
	Limitations to physical activity	
	Physical consequences	
	Medication	
Emotions	No impact	
	Fear	
	Other emotions	
Risk Perceptions	Severity	
	Susceptibility	Fracture risk in the next year

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Global Theme	Themes	Sub-themes
		Fracture risk across lifespan
	Comparison to heart disease/cancer	
Medication Beliefs	General medication	Positive or negative medication beliefs
	Osteoporosis medication	Bisphosphonates administration
		Side effects
		Worry about potential side effects
		Concerns about medication components.
		Concerns about the duration required to remain upright after administering bisphosphonates
		Incorrect prescriptions
		Limit on number of doses
		Access to zoledronate
Adherence	Adherence	Good adherence
		Feedback Facilitates Adherence
	Psychological barriers	Refusal to take medication
		Forgetting
	Non-psychological barriers	Side effects
		Change of Routine
	Other factors	Alters the time/day of dose if

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Global Theme	Themes	Sub-themes
		forgets
Relationships	Doctor-patient relationship	Communication
	Social-support	
Recommendations for helping future patients take their medication	Education	Using pictures
	Medication Instructions	Include more information about the long-term effects of medication
	Patient centred care	
	Monitoring and planning	Dosette box
		Set Routine/Plan

6.6.1 Interviews

In this section, data from each of the ten global themes is presented. This includes quotes to represent each theme. Due to the large amount of data generated in this study, only themes which were discussed by two or more people are described (unless stated).

Identity

The global theme *identity* describes how people understand and make sense of the nature of their illness and their symptoms. During the interviews, the majority of participants showed good knowledge of the clinical features of osteoporosis, which is further demonstrated throughout the other themes. They showed an understanding that osteoporotic bones are thin, weak and easy to break and reduced in bone mineral density. Interpretation of symptoms is a key indicator of how a patient understands their condition. While a small proportion of participants were certain there are no symptoms in the early stages of osteoporosis, half of the study participants were unsure. Some reported pain in the early stages and said they disagree with medics when they suggest that there are no symptoms. For example, one participant said she associates osteoporosis with aching.

"I know they say osteoporosis is painless, I can't really believe that." (Participant 14)

As well as reports of pain, one participant reported flaky nails and rotting teeth as a result of having osteopaenia. Some participants were unsure about which of their illness conditions was the cause of their symptoms, e.g. one woman was unsure as to whether arthritis or osteoporosis was causing her back to ache. One participant suggested that she may be hyper-vigilant to symptoms because she had been labelled with a condition.

"I think that because I'm conscious of it, I think any pain that's going on with my back I think, is that it? I think I could be over imagining it." (Participant 7)

Participants also talked about symptoms in the later stages of osteoporosis: painful fractures, loss of height and stooping. Six out of 7 people showed a curved upper spine in their drawings of stick people with osteoporosis. Patients' drawings of osteoporosis were also indicative of how they viewed their condition. Some examples of these drawings are presented below.

6.6.2 Patient drawings

All patient drawings are presented in APPENDIX 7 and APPENDIX 8. The author looked for potential new/additional information that the drawings may have revealed about the patients' understanding of their illness. The drawings of bones with and without osteoporosis are described below with the following categories: length, shape and bone structure.

Length

The five largest drawings were from participants: 1, 6, 10, 11 and 13. It is important to note that four out of these 5 large drawings were from patients in the DNA group. More differences between attenders and non-attenders are described in the discussion section. Analysis and comparison of the participants' drawings of bones, both with and without osteoporosis, indicate that osteoporosis patients do not view osteoporotic bones to be very different in size to normal bones. This is indicated by the similarity in the length of the longest line through each participant's pair of bone

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sketches (see Table 10). Patients' drawings of bones were measured at their longest point.

Table 10. Longest line measurement for drawings of bones with and without osteoporosis

Participant no.	Bone without osteoporosis (cm)	Bone with Osteoporosis(cm)	Size difference (cm)
1	10	9.9	0.1
2	6.1	5.8	0.3
3	8.1	8	0.1
4	3.8	3.7	0.1
5	5.6	5.9	0.3
6	10	10	0
7	5.8	5.1	0.7
8	3.9	4	0.1
9	4.4	4.5	0.1
10	11	11	0
11	11	11.1	0.1
12	6.8	6.2	0.4
13	10.55	10.1	0.45
14	3.4	1.7	2.7

In the validity exercise, the researchers were able to successfully match patients' pairs of drawings in the majority of cases (only 2 sets of drawings were paired incorrectly). However, they were not as commonly able to identify which drawing was of osteoporosis and which was not. A total of 10 pairs of bones were not correctly

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identified as osteoporotic or not. This highlights that while the bone drawings were similar within participants there was large variability in depictions of osteoporosis.

Shape

Eleven out of 14 participants drew cartoon type bones (see examples in Figure 10). Others depicted the hips (1/14) or the spine (2/14).

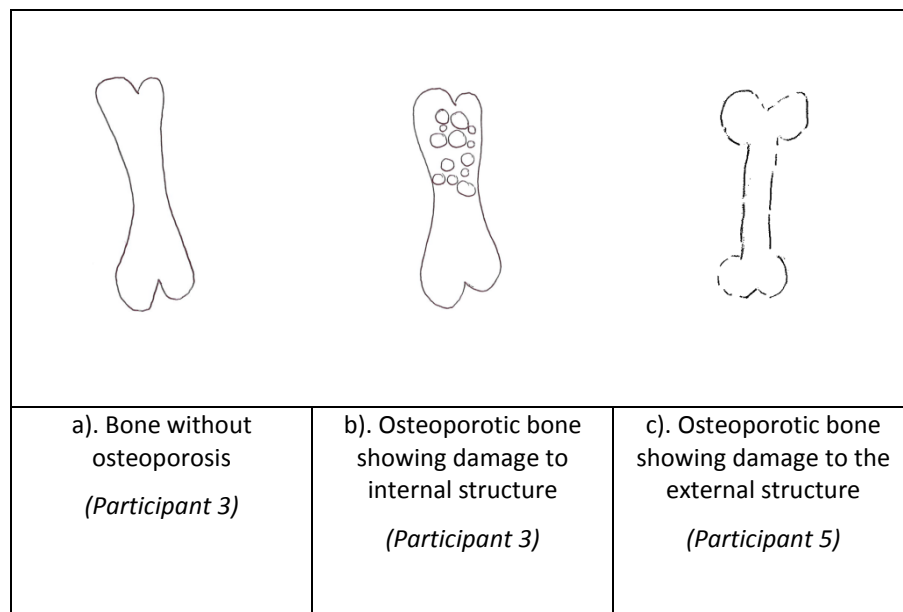


Figure 10. Participants’ drawings of bones with and without osteoporosis

Bone structure/deformity

Some participants drew a deformed internal bone structure 10/14, while others drew a deformed outer edge of the bone (4/14). Only one participant demonstrated damage to both the internal bone and the outer edge. It is noteworthy that the majority of bones drawn without osteoporosis showed an absence of pores. Further, none of the drawings showed fractures.

Drawings of people with and without osteoporosis

Overall, while there was a similarity about the way in which participants drew bones with and without osteoporosis, the pairs of people they drew were very distinctive. The themes highlighted in participants’ drawings of people with osteoporosis were old

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age, infirmity, pain, stooped posture and faint sketches. Similar to drawings of bones, none of the participants focused on fractures. Six out of seven participants depicted curvature of the spine as the deformity in their drawings of people with osteoporosis. Two participants’ drawings emphasised the loss of height attributable to osteoporosis. Participants were more likely to express emotions about their condition when looking at their drawings of osteoporosis than during other parts of the interview. For example, when participant 9 was asked about how osteoporosis affects her emotionally, during the interview she said:

“I don’t really think about it. Accept trying to be a bit careful. But no fortunately I mean I don’t get pain and I don’t get trouble with it.”

However, the drawing exercise provoked other feelings about her condition:

“I’m very cross that I’ve got this awful shape and my friend, my son’s partner says stand up straight, she’s a yoga teacher. Well I can stand up straight. I find myself standing (bent). Why? Because I feel comfortable. Why that should be I don’t know.”

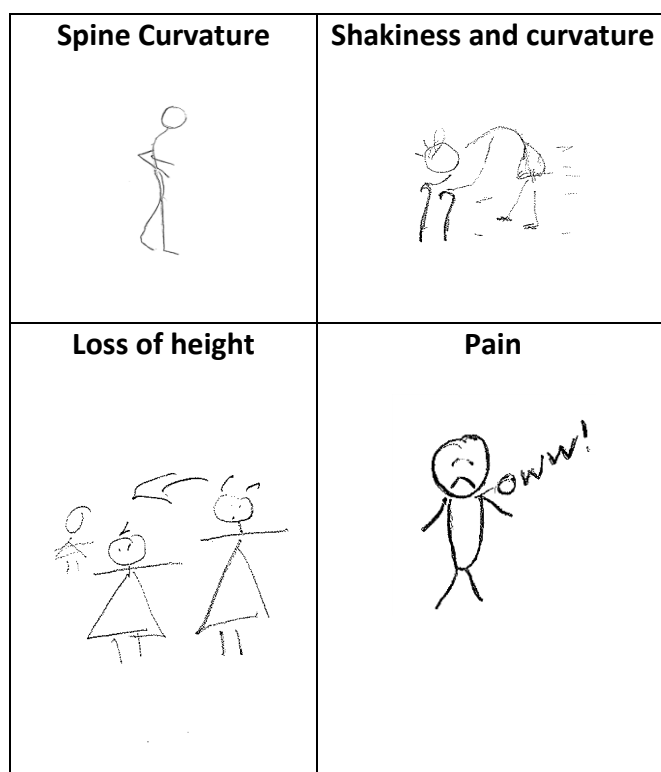


Figure 11. Patients’ drawings of people with osteoporosis

6.6.3 Interviews Continued

Cause

Exploration of causal attributions for osteoporosis and fractures are described in this theme. Participants were asked about the causes of osteoporosis in general, as well as the cause of their own osteoporosis. Though participants were able to list some causes of osteoporosis in general, they usually struggled to identify a cause for their own osteoporosis. The majority of the participants' responses about causes of osteoporosis could be categorised as modifiable and un-modifiable causes.

When asked about the causes of osteoporosis in the general population, the modifiable causes most commonly reported were a diet low in calcium and vitamin D. Participants also identified smoking, weight, exercise and the idea that society as a whole is less active in general, as contributing factors which may result in osteoporosis. The un-modifiable causal factors discussed included: heredity, aging, small (thin) bones, hormonal causes (post-menopause, early menopause and hysterectomy) and in one case post-partum osteoporosis.

While participants demonstrated an understanding of the causes of osteoporosis in general, they were often unable to identify the cause of their own osteoporosis. Just over a third of participants reported that they did not know the cause and said they had not previously thought about it. Participants who answered the question about the cause of their own osteoporosis often said heredity. Other factors participants discussed as potential causes of osteoporosis, which were difficult to classify as modifiable or un-modifiable were; osteoporosis which is secondary to other medical conditions and stress. The following quotes demonstrate participants' uncertainty about what caused their own osteoporosis.

"Well I mean I honestly don't know, I would have thought something to do with how you live, how you eat, how you drink. But quite frankly in my case I've always been very comfortable...So I would have thought that I had a very good diet. Always. So I don't know what happens, or whether it's heredity I truly don't know." (Participant 14)

Participants were asked if they had suffered any fractures and those who had were asked to describe what they believed to have caused these fractures. Some

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participants attributed their fractures to factors other than osteoporosis; they believed their fractures were due to falls or other medical conditions e.g. glaucoma which meant their fracture was caused by low visual acuity. This is illustrated below:

“I think anyone who would have fallen like that would have fractured. It was a hard fall. I am not able to see all that well so I think this is why I fell over.” (Participant 2)

Many participants described confusion about the cause of their fractures. A common reason for this confusion was because not only do people without osteoporosis suffer from fractures, but conversely not all fractures are a result of osteoporosis. One participant described her uncertainty about the link between osteoporosis and being clumsy.

“I’m quite a clumsy person, I’m always rushing here, rushing there and forget to move my feet sometimes, so you know I am prone to, I feel, I am the sort who is prone to having accidents. And that’s frightening and I really don’t know, I don’t know whether osteoporosis would be cause of that or not.” (Participant 8)

Timeline

This theme describes how long patients believed they would have their condition for and how long they will need to take medication for it. The vast majority of patients understood that they would have osteoporosis for the rest of their lives.

“Until I die.” (Participant 14)

“Forever. It’s never going to go away.” (Participant 3)

“You don’t get rid of it, do you?” (Participant 12)

However, some participants talked about confusion regarding how long they would have osteoporosis. This confusion was in relation to the fact that they are only required to take their medication for a relatively short period of time.

“I think I will have it for the rest of my life. Actually, I am a bit confused by this because the doctor gave me medication last week and told me to take it for two years. I would have thought I would have to take it for the rest of my life.” (Participant 2)

Controllability/Cure

This theme describes the level of control patients feel they have over their condition. Controllability/Cure was divided into 3 themes: feeling in control, confusion about control and fracture prevention.

Most participants were able to list many things that people could do to prevent fractures. The most common was falls prevention; taking extra care to prevent themselves from falling over. It was common for participants to say they would stay at home to avoid adverse weather conditions such as snow. Other methods of control included diet, vitamin supplements, sunlight and wearing a corset to support the spine. Participants also discussed exercise, where some but not all knew that specifically weight bearing exercise is needed. Some participants also talked about specific posture exercises and about using balance training to help them become steadier in order to prevent falls.

“Well, when you go out and it’s wet and you’re always careful you know, people might think, oh dodderly thing, walking along but you have to be careful, you know. In case you slip over if you’re going up steps, or and I try not to go out in the snow or anything like that.” (Participant 11)

“I’m always conscious that I must be careful, that’s the thing I live with.” (Participant 9)

However, when asked directly what they could do to control their own personal osteoporosis, many were unsure. One patient suggested that one can never be in complete control of falls prevention.

“I’m not sure about that, em, so they say. But em. And my mum clearly was told it was preventable and get your children to take action and that’s why I have. I’m hoping it’s a controllable condition, but I don’t know. There seem to be an awful lot of people with it. And you know, you see these self-help things, like take some pills or take exercise but do they know that that prevents it? I’m not so sure about it.” (Participant 13)

“Then you, you never can stop falling over, accidents are going to happen aren’t they, you know.” (Participant 9)

It seems that participants found it difficult to understand how methods of control could be linked to improving the risk of fracture. One participant reported that she had

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never been given any dietary information, so she thought there was no link between osteoporosis and diet.

"Nobody's ever said to me, if you did this or did that, or ate this or ate that, nobody's ever given me a diet sheet, connected with it, so presumably the powers that be don't believe diet has anything to do with it because nobody's ever given me anything to say do this." (Participant 8)

Similarly, one participant could not understand the link between exercise and osteoporosis.

"I mean you can exercise, but if it's leaching from your bones I don't know how exercise could make it stronger. Nobody has explained that so far." (Participant 10)

An important issue expressed by many participants in this study was the difficulty in controlling osteoporosis, particularly in cases where some individuals are suffering from multiple co-morbidities. Participants reported difficulty in managing other health conditions whilst simultaneously managing osteoporosis. Participants discussed how they feel torn between multiple conditions when trying to control them.

"It's all about probabilities, it's you know, do I take statins so I can eat cheese so that I can have calcium and not have osteoporosis...is a complicated thing." (Participant 13)

"I used to eat a lot of cheese, but then I've had to cut down on that because of my cholesterol, so er you're between the devil and the deep blue sea sometimes." (Participant 4)

Uncertainty about how to control osteoporosis was further highlighted by some patients who reflected questions back to the author with a variety of questions related to how to control osteoporosis.

"Have you come across anything about exercise making your bones stronger?" (Participant 10)

"I don't know, is weight a burden on the bones, or do they need a bit of weight to be good bones? I'm too ignorant about it." (Participant 8)

"Does walking help do you think, that's what I think but is it true?" (Participant 11)

It seems that in a condition with no cure, it is difficult for patients to understand that there are ways of managing the condition and stopping it from getting worse. All

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participants were aware that there is no cure for osteoporosis, though some said that they hoped for a cure in the future.

“Oh yes, I am certain there will be a cure, I don’t know, my general feeling is that.”
(Participant 8)

“Not at the moment, but they are coming up with new medications all the time so there may be one day...I hope.” (Participant 2)

“I don’t see how it can be cured; there are too many bones in the body.” (Participant 9)

Participants were also asked about the role of medication in controlling fractures, in particular whether they thought medication could prevent fractures. Half of the study sample reported that they had not thought about the possibility of medication in reducing or preventing the risk of fractures, or that medication cannot prevent fractures.

“No, it would be unfair to say I’d ever connected it really.” (Participant 8)

“Er, I’m not sure. I don’t think it could stop a fracture. A medicine could not stop you from falling down.” (Participant 2)

Half the participants believed that medication could control osteoporosis. However, only 2 participants could clearly state that medication reduces fracture risk. For other participants it seems that they had only made the connection between medication and fractures during the interview.

“Er, I think it’s proven that some medications reduce the risk of fractures. And I guess there is also the effect of, if you’re taking medication for osteoporosis, it will automatically alert you to be a bit more careful than you otherwise would be.”
(Participant 3)

“Well I think I suppose it makes it less likely that if you fell over and hurt yourself that the result would be a fracture.” (Participant 12)

Consequences

The consequences of having osteoporosis most commonly described by participants were: limitations to their physical activity, medication and physical consequences. Generally participants reported that having osteoporosis did not have much impact on

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them and that they did not think about the condition every day, though some said that it limited their physical activity. As well as mentioning that being more careful is a method of controlling osteoporosis, participants noted that it limits their activity by causing them to be careful. Some participants reported that age would make them careful anyway, regardless of osteoporosis.

“But physically, you know I still mow the lawn. But I wouldn’t do something like cycling. I used to ski, I wouldn’t dream of doing that, anything that involves you know, ice-skate. So it limits my mobility to a certain degree and it limits what I can carry. Carrying stuff is less easy than it was that’s for sure.” (Participant 3)

“Well I mean, if I’m getting up on a ladder, or if I do anything, I hang on like mad and so on. I suppose I might do that at my age anyway, thinking about it.” (Participant 5)

Many participants reported that osteoporosis did not have much effect on their daily lives. Some participants said that the only consequence of the condition was the requirement to take medication.

“It doesn’t affect me at all, I have no symptoms. The only way it affects me is that I have to take medication.” (Participant 1)

“It doesn’t really; apart from it does mean that I have to take pain medication every day. I can’t go through a day without pain medication, you know I’ve been on the whole range.” (Participant 3)

The physical corollaries participants discussed were: upper spine curvature, loss of height, hospitalization, brittle bones, disability and chronic pain from fractures. The majority of participants discussed curvature of the spine (kyphosis), especially when asked what osteoporosis is. Few participants noted mortality to be a possible or indirect consequence of osteoporosis. Participants’ drawings of osteoporosis further highlighted the perceived consequences of the condition. These are discussed in the drawing section below.

“I think, people develop this what I think they call the dowagers hump, which is due to fractures, I think, of the spine and they sort of begin to shorten as it were and I think that has been my worst worry, is how it would affect my spine eventually, because I do tend to suffer with back ache.” (Participant 1)

Emotions

Over half the participants said they did not feel strong emotions about the condition, reporting that this was the case because osteoporosis was not a main feature in their daily lives. In answer to the question of how osteoporosis affected them emotionally, participants commonly reported that they didn't think about osteoporosis much. Many participants reported feeling lucky that their osteoporosis was caught early and being managed.

"I don't really think about it. Accept trying to be a bit careful. But no fortunately I mean I don't get pain and I don't get trouble with it." (Participant 9)

"Actually I feel quite optimistic about my osteoporosis if you like because I know I'm being treated." (Participant 12)

However, these reports of a low emotional response and feeling lucky were contrasted during discussion with patients' of their drawings of the condition. While at some points during the interview participants reported that they did not think about their osteoporosis, on occasion whilst talking about a different subject, some reported that having osteoporosis was very worrying. Many fears were discussed by this group, including fear of becoming wheelchair bound, fear of fracture, fear of falling and fear of kyphosis. Other emotions discussed were shock, worry and anger.

"So if I fractured my spine, I could end up in a wheelchair couldn't I? Which is my biggest fear." (Participant 4)

"If you asked me what I thought about it, for me, curving that's the thing that worries me most." (Participant 9)

Risk perceptions

To explore patients' perceptions of their risk of fracture in osteoporosis, patients were asked to think about both osteoporosis in general and their own osteoporosis. When asked about the seriousness of osteoporosis in general, all participants reported that osteoporosis is a serious condition.

"Well yes, it is a serious condition I think, mainly because of fractures and the disability it causes." (Participant 1)

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"I think it's really serious because it just affects your quality of life so radically."
(Participant 13)

However many also reported that their own osteoporosis was not severe. Some patients were unsure about how serious it was for them personally.

Participants were also asked about their susceptibility to a) a fracture in the next year and b) a fracture in their life time, compared to other men and women of their age. There were a range of answers about susceptibility to fracture. It was most common for participants to report that their fracture risk was the same or lower than that of other men and women of their age. Interestingly, some believed that their fracture risk was lower because their osteoporosis had been identified, in comparison to others who have the condition but it remains undiagnosed.

'Well I mean you never know who is going to be hit by a bus, this would cause anyone to fracture, so I'm not at more risk.' (Participant 1)

My fracture risk is less because "(a) I'm on zoledronic acid, (b) I take vitamin d and (c) I'm careful. So another 60 year old who was not aware that they might have osteoporosis bubbling around, in the background, probably stands a greater risk of fracturing something than me." (Participant 3)

Some participants reported that their fracture risk was higher than that of other people their age, because their active lifestyle could result in greater risk than for someone who was less active than them.

"Well it's probably more likely because I do a lot more. I'm not a stay at home and watch the telly all day sort of person." (Participant 9)

However, there were other patients who were much less able to talk about their future fracture risk, including some who said that they did not like to think about their risk.

"I suppose you're making me think about things I don't really want to think about."
(Participant 8)

Participants were also asked about how serious they thought osteoporosis was in comparison to two other medical conditions; heart disease and cancer. While the

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majority thought osteoporosis was less serious than heart disease or cancer, some believed it to be equally or more serious.

“And when I see people who are totally crippled, I can remember the doctor saying, there’s a lot of things as bad as cancer in this life. I totally believed him. I would put it on a par with any of those serious illnesses.” (Participant 14)

“Well, if you’ve got cancer, you’re ill and that’s it, but you can have osteoporosis all your life can’t you.” I’d rather have cancer. It’s quicker. If you’re gonna do it you might as well do it properly.” (Participant 5)

Medication beliefs

There was variation in participants’ responses to the question, is medication in general positive or negative? Half of the study sample said medication was positive.

“I’m not the least bit thoughtful about medication and I just think side effects, any side effects are probably not as bad as if you don’t take it and you miss out on some advantage of the medication.” (Participant 3)

However, half of the participants listed various concerns about medication in general, particularly about: side effects, harmfulness, over-prescribing, addiction, suspicion of pharmaceutical companies, dislike of chemicals, drug interactions and overdosing.

“You know even if you are taking Lemsip, I don’t think you should be taking one every hour, because it says that clearly. You should take it every 4 hours and paracetamol is really bad for you if you overdose on it so you know, I think you need to treat it with respect...they’re not sweeties.” (Participant 12)

“Doctors are enthusiastic to give medicines because that’s what they do. I am keen to kind of make sure that it’s what I really need, so I’m kind of negative really.”
(Participant 13)

“If you can avoid medication I think you should. Because medication, whilst it might be good in some respects, it’s not natural, is it? You’re putting things into your body and I would avoid that if I could. But I do understand that there are occasions when you don’t have a choice really.” (Participant 5)

“Because it must harm the insides somehow to keep taking pills. And if you’ve got a few things wrong with you and if you’ve got all these things mixed up inside, all these different problems, surely in the long run it don’t help.” (Participant 11)

“But all medicines are poisons aren’t they?” (Participant 12)

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There was a range of responses about how easy osteoporosis medication is to administer. Most participants commented that it was easy to take.

“The whole standing up thing is rubbish, because you know by the time you’ve taken your medication you clean your teeth, you make your bed, you fill the washing machine. So there’s no big deal about standing up, it’s not like I’m standing up thinking I can’t sit down. All you can’t do is take it and lie down. So, it’s not onerous because that’s what you do, you take your medication, you clean your teeth, you wash your face. Change your clothes, sort out the washing, make your bed.”(Participant 12)

However, some participants commented that it is frightening to take, because of the fact it is dangerous if it gets stuck in the oesophagus.

“And I did once get it stuck in my throat and I can remember thinking that was just, I was jumping up and down and panicking and my oesophagus got kind of, you know went into spasm because I was frightened and em, doing that every day was unpleasant.” (Participant 8)

Two participants commented that while they found osteoporosis medication easy to take, their relatives who also had osteoporosis and were older found it much more difficult and misinterpret the medication administration instructions.

“You do, you only take it once a week and it’s horrible. You have to sit upright and drink this stuff and it’s like an acidity sort of stuff. You then drink water to make it go down. She was very bent and crippled and it’s very hard to make stuff go down.” (Participant 13)

“Elderly people do not like doing that, they find it very difficult to comply, because they just can’t, you know they think from the instructions... one thing and another and she reads that as I have got to sit upright for half an hour in bed for one hour after taking it with water.” (Participant 3)

The following will illustrate the specific concerns highlighted by participants in relation to osteoporosis medication. These included: concerns about side effects and dislike of using unnatural substances, the duration of remaining upright after taking medication, potential side effects, incorrect prescriptions and specific medication components. Many participants talked about the experience of side effects as a barrier to medication-taking.

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"So I took Fosamax (bisphosphonates) for 9 months and in that time, it changed my digestion completely...so I was getting reflux." (Participant 5)

"The components of bisphosphonates are not a lot different to the chemicals they use to clean machine parts." (Participant 7)

"Er a friend of mine who has been on it for many many years before me, er she was told 2 hours by her doctor, so I queried that with my doctor and she said well half an hour should be enough, an hour if you really want to, but I think 2 hours is excessive to stand or sit." (Participant 8)

"I'd read the leaflet about the oesophagus and er, a friend of my husbands, his wife had just died with having cancer on the oesophagus. And it was pretty awful evidently, so I thought, I don't fancy that...Yeah, the thought of it. It probably doesn't happen to many people, but once you start getting any sort of side effects, you think, oh maybe it's doing it to me." (Participant 5)

One of the participants refused to take bisphosphonates because they contain aspartame, which she believes to be harmful.

"When I researched it, it did say it contained aspartame and I understand aspartame to be quite a deleterious compound. And it strikes me quite absurd, because it's not necessary in any way for osteoporosis, it's just a sweetener, em and I'm fairly convinced I don't know want to take aspartame on daily basis." (Participant 7)

One of the participants explained that this medication was incorrectly prescribed, because she had previous problems with indigestion.

"I thought my indigestion wasn't bad enough to make a difference and when I realised it did make a difference, I thought I'm gonna stop now, because it seems a bit stupid...because it says on this piece of paper, if you have indigestion don't have it, so I probably shouldn't have had it in the first place." (Participant 5)

While most of the patients did not doubt the efficacy of the medication and were keen to follow their doctors' advice, one did doubt the efficacy of osteoporosis medication.

"I don't believe that they necessarily improve bone density, I think they give you higher bone density readings. I'm not convinced they give you higher bone density." (Participant 7)

One participant discussed how it was due to her upbringing that she was not keen on taking medication.

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"I don't know. Erm, I suppose it is just inbred, I come from a generation, I mean, my mum's generation-they have never taken a tablet in their life." (Participant 5)

One participant said there is a limit on the amount of doses of bisphosphonates that can be collected from a pharmacy at any one time, which makes collecting her prescription inconvenient.

"I think they maybe have controlled how many they can provide, because although I've sometimes asked for 3, I've only been given 2 boxes...they do not marry up with the other prescriptions I take. Its nicer to get all my prescriptions in one go, but I can't get those aligned." (Participant 6)

Adherence

The majority of patients reported excellent adherence to their osteoporosis medication.

"Let's say I took it for 6 years, I might have missed it 3 times" (Participant 8)

In contrast, a few patients reported some non-adherence. The reasons given for non-adherence were classified as intentional and unintentional. The most common reason for which patients reported non-adherence was side effects. One patient was thinking about whether to initiate osteoporosis medication and one patient refused to take osteoporosis medication even though it was recommended by her doctor.

"No, no, I will never take bisphosphonates" (Participant 7)

The most common reasons given for omitting doses were unintentional, including: side effects, forgetting, altering the time/day of the dose and change of routine.

"You know if you get up and do other things and you forget, that's when you forget and then, you know maybe em, very rarely I forget. Very rarely. But I do forget, say once a month I might forget to take that days tablets." (Participant 11).

Some patients reported having to stop taking it due to fear of potential side effects.

"And then I stopped taking them, I thought I'll just get indigestion." (Participant 14)

Other patients discussed how a change of routine interfered with their medication-taking regime.

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"I missed the dose because I was out, I wasn't in my house and I was away. So a change in routine meant I couldn't do it. Usually I have it with me, but I was unexpectedly delayed so I missed it, you know." (Participant 12)

Relationships

The healthcare professional-patient relationship featured in all participants accounts of factors which influenced adherence to medication. Some participants reported that they had a good relationship with their doctor, which made it more likely for them to follow their doctor's recommendations.

"I've got a very sympathetic doctor, he'll talk to me and listen to me and if he says do something, I'll do it you know" (Participant 9).

Some participants talked about a negative relationship with their doctor, exacerbated by: lack of time during the medial consultation, poor communication, lack of continuity of care and lack of a particular doctor's knowledge of osteoporosis.

"I mean I had a 15 minute appointment, of which he spent 10 minutes talking to somebody else and he did apologise and I spent 5 minutes with him and that was it, goodbye. And I thought I've wasted my time coming up here." (Participant 10)

"I think you're treated in quite a childlike way, you've got to stand up for an hour. Okay, I can do that, why?" (Participant 7)

There was one particular patient who was very confused by some conflicting information she received from two healthcare professionals. She had surgery on her broken ankle and after the operation the surgeon told her that her bones had the consistency of cheese and to initiate anti-osteoporosis medication immediately. However, she subsequently had a BMD scan and it was revealed by another osteoporosis consultant that her BMD was not in the osteoporotic range. She wrote to the surgeon to ask what he had meant regarding the consistency of her bones and why she was prescribed osteoporosis medication, because it did not correlate with her BMD scan or her osteoporosis consultant's advice. The surgeon did not reply to her request for information. This conflicting information resulted in difficulty for the participant to understand her bone health.

"I don't really understand in the scheme of things how strong or not strong my bones are, cos you've got the surgeons who have actually been in there, who have said, these

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are cheesy, em and em, Dr X saying from the x-ray you don't look like that"
(Participant 8)

Social support was also discussed as a factor which could influence adherence. Many participants reported being reminded to take their medication by their families and being prompted to go for osteoporosis screening.

"I just remember on a Sunday morning I have to have it and my husband now he's got into the habit – have you had your medicine? And then sometimes I say oh no!"
(Participant 4)

"She was very anxious that her daughters in particular should not suffer and she's quite an assertive person you know who, really didn't want us to go through what she had been through. And wanted prevention, so she was pushing us the whole time to do it"
(Participant 13)

There is another example of social support where a participant told her mother not to take osteoporosis medication.

"They started to give her risedronate, but I mean needless to say, all the, you know you've got to sit up for half an hour and blah blah all that kind of stuff every Saturday morning and, she just didn't, she couldn't comply with it and so I just said forget it, you know and in fact you know both her ankles healed very quickly and very well."
(Participant 3)

Comparison between attenders and DNA's

There were some important differences between attenders and non-attenders in relation to some themes. The most striking difference between groups was related to medication beliefs. In this study, four out of six patients in the DNA group had concerns about medication, in comparison to one out of nine in the attenders group. Only one out of six of DNAs reported that medication in general was positive. While the majority of participants reported that their chances of suffering a fracture were the same as other women of their age, patients in the DNA group were more likely to report that their risk of fracture was higher (four out of six). Following on from this, the non-attenders discussed more negative emotional reactions to osteoporosis than non-attenders.

Recommendations for helping future patients to take their medication

Participants were asked to provide recommendations to help osteoporosis patients improve their medication-taking. Their recommendations were categorised into 4 themes: Communication and education, monitoring, planning and other. May participants discussed the importance of patients being better informed about their condition:

"I just was given last Christmas er a hand held Dyson by one of my sons and there's no er explanation there, how to use it, it's all pictures. Following the pictures is so easy... I'll tell you what's interesting about that, he doesn't have to do it in all different languages. Because it's all pictures and there should be you know, you've got me to draw a stick person here, somebody could draw a head and a, you know an oesophagus going down to the stomach and whatever, people would understand. It's the not being able to understand that is frightening." (Participant 8)

"Well I think patients need to be as well informed as possible about their illness and the importance of taking medication. I think if patients understand their illness and that their bones could deteriorate without medication, they will take their medication." (Participant 1)

"I think explain to them the reasons for taking medication in a particular way, would be helpful, so the across the board medications like risendronate, alendronate and all the rest of it, that have to be taken at a certain time and you have to sit up and all this kind of stuff. The reasons for that are not necessarily explained to people, they are simply prescribed to them." (Participant 3)

"It's the same with almost everything in life...you need two people in a room, one who understands how it works and one who doesn't and they need to, it needs to be written by the person who doesn't know any of the biological things. You look in the packet of the alendronic acid or whatever it's called and try reading that. That's written for somebody with a doctorate, or at least a good degree...and a degree in kind of medical terms." (Participant 8)

"I don't know, I suppose er, I don't suppose people always understand the consequences of osteoporosis, it's not apparent. You don't have little red spots. I can bend over; I can do every activity I intend to do. It's a bit of an unseen disease; it hasn't impacted on my lifestyle at present. But I am aware of what could happen, you know, so perhaps people need to be aware of what will happen if they don't take their medication." (Participant 12)

"I don't think people say, well if you take this in the long term, these are the consequences. And I would like more feedback, like that." (Participant 12)

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Many participants mentioned monitoring by doctors and pharmacists would help them to take their medication more accurately - in the form of medication reviews, more scanning and feedback.

“I think I would like more feedback, even from my G.P to say how are you getting on with the drugs, are they okay? I don’t think that I get that really, even though my doctor is quite good, you know. And even when I come here, I don’t think that they said everything’s okay? And it’s almost swept aside and they think let’s not worry.”

(Participant 12)

“Secondly I think em, they should get some feedback, in the way of DEXA scanning. So see whether or not taking risendronate on a daily or weekly basis or whatever it is and complying with the instructions - has that made any difference? And if it hasn’t, why take it?” (Participant 3)

It was very commonly reported that feedback in the form of scans helped participants to know that the medication was worth taking because their condition had improved.

“Well, I think it must have worked because when I had a scan last week they said I had improved. I don’t feel any improvement though.” (Participant 1)

“And we did see the results, it was on paper. That helped.” (Participant 5)

Planning was another common theme for participants, as this helped them to take their medication. It was common for participants to talk about the need for habit and that routine was essential in their medication-taking behaviour. They also suggested pill boxes marked with the day using a calendar to mark the days the medication is due.

“Perhaps get a box like me and put pills in for every day. Or if you can’t do it, the chemist can do it, put the pills in the box for you.” (Participant 11)

“No it must be done at the same time every day, so that it becomes a habit, like cleaning your teeth. If it was at different times you would forget.” (Participant 4)

Another way suggested to help people improve adherence was for health care professionals to provide patient centred care – to let patients feel that they are involved in the decision to initiate medication.

“Me personally, it would be me in the driving seat and saying, I’ve had a big part in deciding to take it. I don’t want to be treated like, I’m the specialist, this is what you

must do, because I don't necessarily. I do trust the specialists, I'm not saying that they are deceiving me, I'm just saying they have an agenda and it might be different from mine." (Participant 13)

6.7 Discussion

6.7.1 Key findings

This qualitative study used two psychological theories and a novel drawing method to systematically explore psychological factors in osteoporosis/osteopaenia. Cognitive and emotional representations of the condition were explored. The study has produced some novel findings about how osteoporosis patients visualise and make sense of their condition. Overall this study revealed a wide range of patients' beliefs about their condition and medication, which included some misconceptions and concerns about the condition and how to manage it. These findings have implications for the design of adherence interventions.

The most striking finding in this study was that many patients did not know or understand that the key function of osteoporosis medication is to reduce the risk of fracture. It was quite surprising that a number of patients did not see a link between medication and fracture risk, or they thought that medication could not reduce the risk of fracture. The implication of this lack of understanding is that it may reduce how much patients perceive the need for medication. A way to communicate and help patients understand the link between medication and fracture risk needs to be developed, as this may improve medication adherence.

In summary of other misconceptions identified, the study confirms that osteoporosis/osteopaenia patients have unrealistically low perceptions of their fracture risk (Giangregorio et al, 2008) and they attribute fractures to causes other than osteoporosis (Giangregorio et al, 2009). Although there was knowledge about some aspects of osteoporosis, including the nature of osteoporosis, the chronic timeline and the consequences, they also demonstrated a low understanding of some important features of the condition. There was confusion about: whether or not there were symptoms in the early stages of osteoporosis, the causes of osteoporosis and fractures and finally the methods of managing osteoporosis.

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This study has produced findings similar to studies of other chronic medical conditions. For example, participants have unrealistically low risk perceptions. This has been explained as a type of optimistic bias (Weinstein, 1989); in which individuals feel less prone to negative consequences than others who are at similar risk to them. In a similar vein, all participants reported that osteoporosis was a serious condition in general, though only one participant reported their own osteoporosis to be serious. Optimistic bias may be psychologically protective, e.g. it would not be helpful to continuously worry about having a fracture. However, low perceptions of risk may be an avoidant coping mechanism, in which a patient avoids facing their high level of risk. Either way, it is important that osteoporosis patients have an accurate understanding of their risk of fracture, so that they can behave in a way to minimize such risks. It was interesting that some participants felt that osteoporosis was more serious than cancer or heart disease, because of the duration and disability they have observed or suffered. This shows that disease severity is not only about mortality, but also about the impact of an illness on the quality of life.

It was interesting that few participants linked their osteoporosis to behavioural and modifiable causes, which could suggest a lack of knowledge, or lack of acceptance that lifestyle choices can impact health. Alternatively, it may be psychologically protective for participants to disavow responsibility for their own behaviour and attribute it to a genetic cause. This has important implications for medication adherence - if patients view the causes of osteoporosis to be genetic rather than environmental, they may believe there is little they can do to control the course of the condition. A further factor which appeared to cause confusion is the cause of fractures, when anyone, osteoporotic or not, can fall and suffer a fracture. The implication of this finding is that education about osteoporosis should include a definition of a *fragility fracture*, which can be sustained on low impact (e.g. walking, lifting) in contrast to a non-osteoporotic fracture.

While some participants demonstrated a good understanding of the asymptomatic nature of osteoporosis, others reported illness related symptoms. The same has been found for other asymptomatic conditions (e.g. Chen 2010). The experience of

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osteoporosis related symptoms is important and it is likely that the perception of illness related symptoms act as a guide to the need for medication. This could be problematic because patients may wait for symptoms before initiating medication, or interpret a lack of symptoms to mean that they are not unwell. Previous research indicates that bodily symptoms both create and update patients' representations of their illness (Cameron & Leventhal, 2003). Further, patients who experienced pain in the later stages of osteoporosis were confused by HCPs claim that osteoporosis is 'silent' or 'painless.' This implies the need for clearer communication that while there are no warning symptoms in the early stages, there are physical signs of the condition in the later stages, e.g. pain, spine curvature and loss of height.

The report of symptoms in the early stages of osteoporosis could be a sign of patients perceiving symptoms as a result of being diagnosed with a medical condition and they are looking for a bodily sign to fit this label. Therefore, they may experience symptoms as a result of being labelled with a medical condition. This phenomenon has been shown in hypertensive patients (Baumann & Leventhal, 1985). It is possible that people find it difficult to understand that they can have an illness with no symptoms, because the disease is invisible and does not appear to affect them. Further, it should be clearly explained to patients that they require medication in the early stages of osteoporosis, even if there are no visible symptoms or signs of the condition. It also needs to be clear to patients that medication is used for fracture prevention rather than symptom alleviation, in order for them to understand the benefit of taking it.

It was interesting to explore participants' causal attributions for their fractures. Corresponding with the findings of previous researchers many participants attributed the causes of their fractures to factors other than osteoporosis e.g. sight problems or falls. French et al (2002) investigated patients' causal attributions for myocardial infarction and found that these patients perceived a range of possible causes of MI, which were categorised by the researchers as proximal and distal. For example, a proximal cause could be stress, while a distal cause could be diet. In this study it appears that patients view the proximal cause of a fracture (a fall) to have more bearing on the outcome than the distal cause (the underlying bone fragility). The fact

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that some participants who had suffered fractures hold a causal attribution of falling rather than osteoporosis is problematic, because it may influence how they choose to manage the condition, e.g. they may choose falls prevention over medication to manage it, when in fact both are needed.

Participants varied in their perceptions of the duration of osteoporosis, with the majority reporting that they will always have osteoporosis. It is positive that the majority of participants understood that they will have osteoporosis for the rest of their lives, because this demonstrates a good understanding of the chronic nature of the condition. However, some participants asked whether there was a cure. The fact that many patients said they hoped for a cure in the future is positive in that they have hope, but problematic where this may have a bearing on how they manage their condition e.g. neglecting management until there is a cure. Some of the participants were also confused that they were not required to take medication for the rest of their lives, even though the condition is chronic. This implies that the reasons for taking medication in the short term need to be clearly communicated to patients- i.e. that bisphosphonates are recommended for 5 years because there are no known benefits of remaining on the medication for a longer duration (Black et al, 2006). It is important that this miss-match in perception of timeline is addressed.

Promoting self-management for patients with chronic conditions is well known to be difficult (Glasgow et al, 2003). Aside from falls prevention, there was uncertainty about how to control osteoporosis among this sample. Previous researchers have found that participants from a non-clinical population were unaware of how to prevent osteoporosis (Williams et al, 2002). Some participants said they were unsure about whether advice they were given about controlling/managing osteoporosis is proven. This is further highlighted by the questions participants asked the author about the condition, specifically in relation to controllability. One participant said she was never given any dietary information, so she assumed there were no specific dietary requirements for osteoporosis. Perhaps this could be addressed by psycho-educational interventions, providing patients with information about how their osteoporosis can be controlled. The misconceptions patients hold about their condition and medication

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could lead to mismanagement of the condition. The implication is that unclear information could reduce the coherence of patient's illness representations, which is theorised to have an adverse effect on adherence (Leventhal et al, 1997).

While this group of patients reported some limited activity as a result of osteoporosis, e.g. difficulty with carrying shopping bags, they were still all fully independent. A few reported that it was age rather than osteoporosis that limited their activity. Perhaps they were reluctant to accept that their medical condition was the cause of them being more careful, creating the necessity to protect themselves from a fall. This could be due to participants trying to normalise what is happening to them, or a denial/lack of acceptance of the limitations of the condition. One participant reported that medication was her only reminder of having osteoporosis. This highlights one of the difficulties of promoting medication adherence in asymptomatic conditions, patients may perceive the medication to result in more problems than it solves.

Previous studies have shown that medication beliefs can predict medication adherence (Carr et al, 2008; McHorney et al, 2007). In the present study, the most commonly discussed barriers to adherence were concerns about side effects, or worry about potential side effects - such as oesophageal damage. Oesophageal cancer is extremely rare and its link with osteoporosis medication was misinterpreted by the media (Cardwell et al, 2010). There is a debate as to whether patients should receive detailed information about potential medication side effects (Wells & Kaptchuk, 2012). While patients have a right to receive all available information about their medication, it is possible that raising the issue of side effects with patients causes some of them to experience side effects. Patients who were administered a placebo and informed that they would experience fictional side effects, commonly reported experiencing these side effects (Benedetti et al, 2007). This shows how expectations about medication can lead to a perceived response.

It was interesting that the patient who had chosen not to take medication indicated major concerns in relation to osteoporosis medication and its efficacy as her reason for her decision not to take it. The same patient reported that she believed that her doctor

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had referred her to this research project as her beliefs were problematic. As a result of her medication beliefs she felt she was being treated as if 'deviant'. This feeds directly into the next paragraph about the doctor-patient relationship.

While patients were not directly asked about this, the doctor patient relationship emerged as an important feature in a patient's decision to initiate and continue with their osteoporosis medication. The importance of this relationship has been documented in various prior studies (Lau et al, 2008; Young & Oppenheimer 2009; Zolnierrek & DiMatteo 2009). One participant received conflicting information from two doctors about the severity of her osteoporosis, this left the patient distrusting her doctor and unsure of her need for osteoporosis medication. Aspartame is a component of bisphosphonates. One participant reported that this ingredient aggravated another of her medical conditions. She contacted her doctor to request an explanation for the inclusion of aspartame in such medication, however, she did not receive a response to this query. This shows patients taking an interest in osteoporosis medication, yet receiving no feedback or support.

Comparisons between attenders and non-attenders were interesting. Negative beliefs about medication were more common in the group of non-attending patients, with four out of five non-attenders in this study reporting that medication in general is negative. Considering that medication beliefs are predictors of adherence (Carr et al, 2006; McHorney et al, 2007), this suggests that these patients may be more likely to miss doses of their medication. This finding is in agreement with previous research from a large study, which has shown that patients who did not respond to questionnaires were more non-adherent than those who did respond (Gadkari et al, 2011). It is interesting that the majority of DNA patients reported that their fracture risk was higher than that of the general population, while the attenders were more likely to report that their risk was the same or lower. Perhaps DNA patients' high risk perceptions indicate their high emotional response to the condition and thus an avoidant coping mechanism such as not attending their appointment with their doctor. This interpretation is backed up by non-attenders describing more negative emotional reactions to the condition than attenders.

6.7.2 Methodological contribution of drawings

The research provides a description of a novel method of investigating how osteoporosis sufferers visualise their condition through the use of participants' drawings. In terms of the SRM, this has allowed detailed investigation of illness 'identity' and emotions. It has been previously documented that drawings activate emotions and cognitions (Bradley & Lang, 1992). Drawing has proved to be useful both in gaining further insight into how osteoporosis patients understand their condition, as well as eliciting their emotional responses to the condition.

Every illness produces a specific, unique set of emotional responses (Fife, 1994). When interviewed, participants were asked to describe how they felt about having osteoporosis, they often reported no emotions. In many cases, before or after the tape recorder was running, patients reported concerns that they would not be a good candidate for the research as they did not worry about osteoporosis at all. It was not surprising that patients reported a low emotional impact of osteoporosis, because of its asymptomatic nature. This highlights how invisible the disease can be to its sufferers. When looking at their drawings and discussing osteoporosis, patients were more likely to report negative emotions such as fear, worry and anger. The contrast in the reporting of emotions across the two mediums; interviews and drawings, could be because drawings make concrete the effects of osteoporosis. The findings of the present study support those of Cameron (2009), who showed that image representations are an important component of an illness risk representation, which can be used to predict health protective behaviours. This highlights the benefits of assessing an emotional response to a medical condition using drawings, which appear to access emotions in a way that interviews alone cannot. The study indicates that drawings can be used to supplement a discussion about how patients feel about having osteoporosis.

Kyphosis (spine curvature) is one of the biggest fears for osteoporosis sufferers (highlighted in participants' drawings). Drawings of people with osteoporosis indicate that these participants are most conscious and frightened of the visible signs of osteoporosis, with the majority depicting kyphosis and no drawings of a fracture. This

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may be because fractures are difficult to draw. Kyphosis does not happen to everyone with osteoporosis and this should be clearly communicated. It is important that the fears raised in this study are addressed – to ensure that patients do not develop avoidant coping mechanisms. One way of alleviating this fear could be to clearly communicate that medication can reduce the chances of fracture and long term immobility, even in the event of a fall. Without the opportunity to depict and talk about the emotional effects of osteoporosis, it is possible that patients will continue to believe the condition to be abstract and asymptomatic. The fact that osteoporosis patients hold visual representations of their illness means that using images to communicate risk may be effective. It proved useful to have a team of researchers to analyse the drawings produced in this study, because interpretation of their meaning is subjective.

The participant drawings produced similar results to those of previous authors who studied visual representations in other medical conditions. Broadbent et al (2006a) reported that the larger the patients drawing of the heart, the higher the cardiac anxiety. In the present study, it was found that the group who produced the largest drawings of bones were also the group who reported high levels of concern about osteoporosis medication and medication in general. This was the DNA group. This has been explained as drawing size increases as the saliency of the object increases (Craddick, 1961; Thomas et al, 1989). This provides support for using images as a method to assess illness representations.

Within participants comparisons of drawings were interesting. Each participant's pair of drawings of bones with and without osteoporosis was drawn very similar in size, which suggests a lack of understanding that osteoporotic bones may be small/thin in comparison to bones without osteoporosis. It was interesting that participants selected stereotypical cartoon type drawings of bones to represent osteoporosis. This suggests that drawings of cartoon type bones could be beneficial materials to use to communicate information about the condition to patients.

6.7.3 Implications for interventions to improve adherence to osteoporosis medication

This section will draw on the findings from this study which can be used to design a psychological intervention to improve adherence to osteoporosis medication. A key component of a successful intervention is to tailor interventions to each individual's needs (Horne et al, 2005). It is important to note that, because patients reported a vast range of various beliefs, the use of tailored psychological interventions is supported. This section will describe the study implications for future adherence interventions.

In relation to strategies for promoting adherence, participants in this study suggested many useful ideas (presented in Table 9). The ideas they generated were similar to those found in previous studies, for example providing more accurate medication instructions, practitioner feedback and support and educational material (Lau et al, 2008). A tailored psycho-educational intervention would be beneficial for patients with osteoporosis, to address patients' misconceptions about their condition and medication. Further, psycho-education is a useful technique to highlight the various methods of controlling osteoporosis and preventing fractures. This study identified many common knowledge deficits. For example, more knowledge is needed on the causes of osteoporotic fractures, which are both poor bone health as well as a precipitating event, e.g. a fall or poor eye sight. This study suggests that general education for patients could focus on the causes of osteoporosis and methods of managing fracture risk. As well as education for patients, HCPs could be educated about the importance of emphasizing adherence to medication.

The most commonly discussed concern about osteoporosis medication was side effects, or potential side effects. It is important that these concerns are addressed—particularly the extent to which patients should tolerate minor side effects. Additionally, medication instructions should be adjusted so that patients understand, for example, that when taking bisphosphonates, it is necessary to remain upright but not necessarily static. Potential interventions to address negative medication beliefs

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include the provision of information about the benefits and barriers of taking medication.

Other findings with implications for interventions include those regarding social support and feedback. The present study has shown how social support has a potentially positive or negative impact on adherence. Improved doctor-patient communication can be incorporated into future interventions, including education for health-care professionals (and medical students) about the impact of the doctor-patient relationship and adherence. The HCP-patient relationship should be supportive and address patients' fears and concerns regarding their illness and medication. Feedback from BMD scans was a crucial motivator of adherence for this group, which was documented in previous research (Lau et al, 2008). Scans provide concrete information about disease progression, which is fundamentally important in a condition which is asymptomatic. Such information could be used as intervention materials in future studies. Another example of providing concrete information about osteoporosis is the use of visual images/pictures of the condition. Patients suggested that visual images of osteoporosis would be beneficial in helping them to have a clearer understanding of their condition.

Non-attending patients in this study expressed more concerns about medication than attending patients. While caution must be applied to making generalisations from this data, it is striking that so many had concerns about medication and indicates a possible association between low adherence and non-attendance. This also has implications for adherence interventions. Non-attending patients could be invited to take part in intervention studies, as this is a way of engaging them and possibly promoting medication adherence.

Limitations

A major challenge in adherence research is recruiting non-adherent participants. This is difficult and it is expected that those who agree to participation in research studies are likely to be more adherent/follow their doctor's treatment advice. In an attempt to overcome this we recruited patients who had not attended their last clinic

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appointment -based upon the assumption that patients who did not attend their clinic appointment were also non-adherent with treatment recommendations. The reason for working with this assumption was to aim to recruit patients who had difficulties with medication-taking, in the hope that these patients could provide some new insight into the problem of non-adherence. Nonetheless, the majority of study participants reported being adherent with their medication regimes. This means we should exercise caution when forming opinions of patients based on their history of clinic appointment attendance. Knowledge of the nature of osteoporosis was high in this participant group. Some of this group had previously taken part in osteoporosis drug trials and were therefore possibly better informed about their condition and the role of medication than the general population.

Conclusions

The extended SRM provided a useful framework to systematically explore the cognitive and emotional factors which may influence adherence to medication, as it has produced some novel findings. The findings relevant for the design of a future intervention to improve adherence are:

- Patients have a range of beliefs about osteoporosis and varying informational needs
- Some patients were unaware that osteoporosis medication could achieve fracture risk reduction
- Drawings of osteoporotic bones and people with osteoporosis aroused emotions for some patients in this study, suggesting that visual images may be a useful method of communicating risk in osteoporosis
- Some patients have limited knowledge/ideas about the causes of their condition
- There was limited knowledge about how to control/manage osteoporosis

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- Patients who fail to attend their clinic appointments may also have concerns about medication – and difficulties with adhering to it.

This study highlights that osteoporosis patient's illness perceptions, medication beliefs, emotional responses and risk perceptions are all factors which may influence the way in which they manage their condition. This study suggests that psycho-education might improve adherence to osteoporosis medication. Before an adherence intervention is fully designed and carried out, there is a need for future studies to develop this with a larger sample size, in order to identify the strength of the relationships between psychological factors and medication adherence. A test of the relationship between various psychological factors and adherence is presented in the following chapter.

7 Study 3: The psychological factors related to osteoporosis medication adherence³

Chapter overview

This was a cross-sectional questionnaire study with a correlational design, which tested the relationship between the psychological constructs of two health psychology theories and adherence to medication. The overall goal was to provide a theoretical underpinning for an intervention to improve adherence to osteoporosis medication. Three different self-report measurements of adherence were used. It was found that patients had a wide range of beliefs about their osteoporosis. The data presented in this study forms the baseline data for the adherence intervention in chapter 9.

7.1 Introduction

Given that psychological factors have been found to predict adherence to medication in a variety of chronic conditions (Weinman & Petrie, 1997), the study was carried out to determine the relationship between various illness and medication beliefs and adherence to osteoporosis medication. While there have been many studies to assess the contribution of psychological factors to non-adherence to osteoporosis medication (reviewed in study 1), there are psychological models of behaviour which have not been applied to this problem with this clinical population.

It would be beneficial to investigate the strength of the relationship between illness representations and adherence to medication in osteoporosis patients before deciding on whether to include illness representations in a psychological intervention to promote adherence. Illness representations can be measured using validated questionnaires such as the Illness Perceptions Questionnaire (IPQ) (Weinman et al, 1996); the Revised Illness Perceptions Questionnaire (IPQ-R) (Moss-Morris et al, 2002), which includes additional scales; emotional response to illness and perceptions of cyclical timeline, or the Brief Illness Perceptions Questionnaire (BIPQ), which uses only one item to measure each scale (Broadbent et al, 2006b).

³ This paper was recently presented at the BPS DHP annual conference (Besser et al, 2013a).

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The Self-Regulation Model (SRM) and the extended SRM have been frequently applied to investigate the problem of low adherence to medication in many chronic illnesses, such as: coronary heart disease (Byrne, 2005), asthma (Horne & Weinman, 2002), chronic pain (Nicklas, 2010) and hypertension (Ross et al, 2004). Variation across medical conditions has been found, in so far as the amount of variance in adherence predicted by illness perceptions and treatment beliefs. For example, the extended SRM did not predict much variance in adherence to medication in CHD (Byrne, 2005). To the author's knowledge, there has to date been no study measuring the illness perceptions of osteoporosis patients using any of the illness perception questionnaires.

In brief summary, two theoretical approaches have been selected to gain understanding of the psychological predictors of adherence. These are the extended self-regulation model (SRM) and the extended parallel process model (EPPM). The authors of the extended SRM propose that a patient's method of coping with a medical condition might be best understood by their cognitive and emotional representations of the condition, whereas the author of the EPPM proposes that a patient's selected method of coping with an illness might depend upon their perceptions of risk associated with the condition.

There is no standardised questionnaire to measure risk perceptions and the measure used will vary depending on the model being used to investigate the problem. Turner et al, (2008) designed a measure to assess risk perceptions about contracting HIV. Turner's questionnaire was adapted for use in the present study with osteoporosis patients.

There is no gold standard method for measuring adherence to medication, because every adherence measure has advantages and disadvantages. While self-report measures have the problem of presentational bias, they are most commonly used due to convenience and with the consideration that no measure of adherence is perfect. The five item Medication Adherence Report Scale (MARS) was used in the present study. The validity of the MARS has been established when used to measure

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adherence in patients suffering from asthma (Cohen et al, 2009), though its validity as a measure of adherence in osteoporosis patients is unknown.

To date there have been no published studies that investigate the illness perceptions of osteoporosis patients using the self-regulation model (SRM); a widely used model of illness representations and coping. Similarly there are no published studies which examined the relationship between EPPM variables and adherence. The application of health psychology theory to the problem of low adherence may give rise to a more detailed understanding of how people with osteoporosis make sense of their illness and medication.

The objectives of the study were to examine the relationship between cognitive/emotional representations of illness and adherence to medication; to compare the predictive power of the extended SRM and the EPPM and to ascertain whether the models can be brought together to form a new theory of health behaviour. The aim of the study was to investigate the relationship between a) illness perceptions, b) beliefs about medication, c) emotional responses, d) risk perceptions and adherence to osteoporosis medication. In total this study investigated the relationship of 20 different psychological factors with self-reported adherence to osteoporosis medication. If any of these psychological factors are identified to have a strong relationship with adherence to osteoporosis medication, they can then be targeted in a future adherence intervention. There is also a need to understand the practical barriers to adherence to medication. An example of this is the inconvenience of the medication regime, considering that some osteoporosis medications are prescribed with stringent requirements, e.g. to fast for two hours both before and after administering it, or to remain upright for half an hour after taking it. If practical barriers to adherence with osteoporosis medication can be identified, they can be targeted in a future behaviour change intervention to improve adherence.

7.2 Aims

The overall objective of the study was to investigate the relationship between various psychological factors and adherence to osteoporosis medication. Using quantitative

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methods, the study investigated illness perceptions, medication beliefs, risk perceptions and self-reported adherence to medication, as well as barriers to adherence in patients with osteoporosis or osteopaenia. Other objectives were to identify psychological variables that could be addressed in an intervention to improve adherence and to test two theories by examining which of their variables were related to adherence. It was anticipated that through the identification of cognitive and emotional representations related to adherence to medication, it would be possible to inform an intervention to improve adherence to osteoporosis medication. Psychological factors from two health psychology theories were investigated, the extended self-regulation model (SRM) and the extended parallel process model (EPPM).

Research Questions

- What is the extent of self-reported non-adherence to medication in patients with osteoporosis/osteopaenia?
- What is the range of illness perceptions, medication beliefs, risk perceptions and emotional responses in osteoporosis patients?
- What are the barriers to taking osteoporosis medication?
- To what extent is adherence predicted by the extended SRM variables?
- Can adherence be predicted by the EPPM variables?
- What are the relative strengths of each model in predicting adherence?
- To what extent does a combination of the extended SRM and the EPPM explain adherence?

7.3 Hypotheses

This paragraph will justify the hypotheses for investigating illness representations, medication beliefs and risk perceptions in the present study. Hagger & Orbell (2003) found a small but significant relationship between illness perceptions and coping.

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Previous work indicates that specific illness representations are related to adherence to medication in other medical conditions, e.g. a chronic timeline (Byrne et al, 2005) and the consequences of the condition (Horne & Weinman, 2002). Leventhal's self-regulation model suggests that emotional responses will have an influence on coping (Leventhal et al, 1984). The critical review (study 1) identified that medication beliefs are strongly related to adherence.

1. Illness representations will have a small but significant relationship with adherence. Greater adherence will be associated with high perceptions of timeline, consequences and emotions
2. Medication beliefs will be associated with medication adherence. Greater adherence will be associated with lower concerns about medication.
3. Risk perceptions will be related to medication adherence. Greater adherence will be associated with higher perceived severity and susceptibility.

7.4 Method

7.4.1 Participants

The study population consisted of female hospital outpatients (n=112) from four London teaching hospitals (mean age 67; range 43-89; SD 10.7). All participants were diagnosed with osteoporosis or osteopaenia. Patients who were prescribed an oral osteoporosis medication (alendronate, risedronate, raloxifene or strontium ranelate) for at least one month were invited to take part in this study. This ensured that participants were able to answer the question 'how many doses have you missed during the last month?' Patients were excluded if they were male, had cognitive deficits which impaired their ability to fill in questionnaires, were not prescribed medication for osteoporosis, were unable to administer their own medication, or were unable to speak English (unless they had a translator with them). Some patients were prescribed daily doses (n=43), others weekly doses of their medication (n=69).

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Participants from two groups were invited to the study; those who attended their last clinic appointment (attenders) and those that did not (non-attenders). The clinical factors recorded for each patient were:

- Total number of fractures
- Number of years with osteoporosis
- Number of medical conditions
- Number of medications prescribed
- Name of prescribed medication for osteoporosis

Participants often did not know exactly how long ago they had been diagnosed with osteoporosis, therefore they were asked to give an approximate time. The socio-demographic variables included were:

- Age
- Nationality
- Occupation
- Social support (determined by the number of people with whom they were cohabiting).

Over half of the study participants were aged over 65 (55%). Thirty eight per cent of the sample was retired and just over a third of them lived alone (35%). The majority of the participants were British (72%) or European (9%). The majority of participants had sustained at least one fracture (57%) with the number of fractures ranging from 0-10. There was a wide range of time within which participants had suffered with osteoporosis which ranged from less than one to 31 years. The majority of participants (89%) had another medical condition as well as osteoporosis and 60% were prescribed two or more medications. Patients were prescribed the following oral treatments for

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osteoporosis: Bisphosphonates (n=69), strontium ranelate (n=41) or raloxifene (n=2). A summary of the study participants' demographic and social context data is provided in Table 11.

Table 11. Study 3 and 4 participants' demographic and clinical descriptive data⁴

	Age	No. of fractures	No. of years with osteoporosis	No. of medical conditions	No. of prescribed medications
Mean	67	2	7	3	5
Median	67	1	5	3	4
Mode	65^a	0	5	3	3
Std. Deviation	10.79	2.05	5.84	1.88	3.84
Range	43-89	0-10	1-31	1-11	1-21

^a multiple modes exist. The smallest value is shown

7.4.2 Measures

Six questionnaires with a total of 20 scales were used to investigate psychological factors and adherence. These measures and their scales are outlined below, with example questions from each scale shown in Table 12. Likert scales were used to measure responses, ranging from 1-5, where 1 = strongly agree and 5 = strongly disagree (unless stated). Questionnaires were completed by participants in the order they appear below.

⁴ All scores are rounded up or down to their nearest whole number, with the exception of SD which is rounded to two decimal places.

The Illness Perceptions Questionnaire Revised (IPQ-R) (Moss-Morris et al, 2002) (shown in APPENDIX 11)

This is a widely used validated scale that measures cognitive and emotional representations of an illness using 9 scales. The IPQ-R is demonstrated to be both a reliable and valid measure of illness perceptions (Moss-Morris et al, 2002). This questionnaire was derived from the theoretical constructs described in the self-regulation model (Leventhal and Nerenz, 1984) and is an extension of the illness perceptions questionnaire (Weinman et al, 1996). The questionnaire was adapted for use with osteoporosis patients by changing the word 'illness' to 'osteoporosis'.

The scales of the original IPQ (Weinman et al, 1996) were described in a previous chapter (see chapter 3). The IPQ-R is an amended version of the IPQ, to include three additional scales; emotions, coherence and cyclical timeline. Personal control was subdivided into personal control and treatment control (Moss-Morris et al, 2002). High scores indicated: a greater number of perceived symptoms, strong perception of cause, perceived chronic timeline, high consequences, high perceived personal and treatment control and high emotional response. In some instances, the phrasing of an item required that the scoring be reversed to maintain consistency in the meaning of the item e.g. where strongly agree denoted a negative score. For this reason, 11 items were reverse scored (for details of questionnaire scoring see APPENDIX 17).

The Beliefs about Medication Questionnaire (BMQ) (Horne et al, 1999) (Shown in APPENDIX 13)

There are two parts to the original BMQ; the general and the specific. The general refers to beliefs about medication in general and was excluded from the present study. The BMQ specific was adapted for use with patients prescribed osteoporosis medication. There are two scales in this questionnaire: *Necessity* (5 items) and *Concerns* (5 items). A high score indicates high perceived necessity for medication and a high level of concern about using the medication (for details of scoring see APPENDIX 17).

The Risk Perception Questionnaire (RPQ) (shown in APPENDIX 15)

The RPQ is based upon the extended parallel process model (EPPM) and was adapted from a previous study (Turner et al, 2008) for use with osteoporosis patients. This questionnaire has 5 scales which are measured by 12 items. The scales are severity (2 items), susceptibility (2 items), self-efficacy (2 items), response-efficacy (2 items) and motivation (1 item). High scores indicate: high perceived severity, high perceived susceptibility, high perceived self-efficacy, high perceived response-efficacy and high motivation. It includes questions such as ‘I believe that AIDS is a serious disease’ and ‘I feel frightened of AIDS.’ This measure has been adapted to use in this study to investigate risk perceptions in osteoporosis patients (see APPENDIX 15).

Table 12. Example Questions/statements for each questionnaire and scale

Questionnaire	Scale	Example question or statement
IPQ-R	IPQ Identity	Have you experienced pain recently? Was this pain related to your osteoporosis? Was this pain related to your medication for your osteoporosis?
	IPQ Psychological Attribution	My mental attitude e.g. thinking about life negatively
	IPQ Risk Factor Attribution	Diet or eating habits
	IPQ Immune Attribution	Poor immune system
	IPQ Chance Attribution	Chance or bad luck
	IPQ Timeline	I expect to have this osteoporosis for the rest of my life
	IPQ Consequences	My osteoporosis causes difficulties to those who are close to me
	IPQ Personal	The course of my osteoporosis depends on

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Questionnaire	Scale	Example question or statement
	Control	me
	IPQ Treatment Control	The negative effects of my osteoporosis can be prevented (avoided) by my treatment
	IPQ Coherence	My osteoporosis doesn't make any sense to me
	IPQ Cyclical Timeline	My osteoporosis is very unpredictable
	IPQ Emotions	Having this osteoporosis makes me feel anxious
BMQ	BMQ Necessity	Without my osteoporosis medicine I would be very ill
	BMQ Concerns	I sometimes worry about the long-term effects of my osteoporosis medicine
RPQ	RPQ Severity	My osteoporosis is a serious disease
	RPQ Susceptibility	I feel that I may get a fracture in the future
	RPQ medication-efficacy	I am protected against fractures if I use my medication
	RPQ Self-efficacy	I can use osteoporosis medicine without difficulty
	RPQ Emotions	I feel frightened of having a fracture in the future
	RPQ Motivation	I intend to take my osteoporosis medicine as prescribed

Three self-report measures of adherence

The Mediation Adherence Report Scale (MARS) (Horne, 1997b) (See APPENDIX 14)

The MARS is a validated scale (Horne et al, 1999) with 5 items. Likert scales were used to measure responses, ranging from 1=Always to 5=Never. A high MARS score indicates good adherence, therefore 25 denotes full adherence. Previous studies have

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used a very stringent cut-off of 23/25 to delineate full adherence from partial/non adherence. The rationale for this stringent cut-off is that non-adherence is very difficult to detect/measure.

Percentage non-adherence (APPENDIX 14)

The second measure of adherence was the following item, 'how many doses of your osteoporosis medication did you miss in the last month?' The author added this item to the end of the MARS questionnaire. The number of missed doses was then converted to a percentage of non-adherence score. To calculate percentage non-adherence, the number of missed doses was divided by the number of doses required and multiplied by 100. A high score indicates low adherence.

The Difficulties Of Taking Osteoporosis Medication Questionnaire (DOTMQ) (APPENDIX 16)

The DOTMQ was designed for this study with 14 barriers to medication listed and space for free text to identify barriers to taking osteoporosis medication. Participants were asked to tick items which they felt stopped them from taking their medication. The 14 items were selected based upon the barriers reported in study 2, as well as those commonly documented in the literature. However, only seven items were used in the analysis (see Table 13) because the other seven items overlapped with those of the BMQ or RPQ, e.g. did not think necessary and do not want to take this medication. This questionnaire was designed to capture an individual's specific barriers to their medication, so that they could be targeted in a future intervention study. The measure originally included items about beliefs, motivation, side effects and practical barriers. However, it was decided to remove the beliefs, motivation and side effect items and to use the total number of practical barriers as a proxy measure of non-adherence. Because the DOTMQ was used as a dependent variable, the items which overlapped with items in the former questionnaires (IPQ, BMQ, RPQ and MARS) were excluded. To calculate the 'total barriers' score, participants scored one for each barrier they reported. Therefore a high score indicates a high number of perceived barriers to medication adherence.

Table 13. Practical barriers of taking osteoporosis medication

Difficulties of taking osteoporosis medication questionnaire	
Interferes with daily activities	Hard to swallow
Do not like the taste	Not feeling well
Was not at home	Ran out of medication
Forget	-

7.4.3 Procedure

Ethics

Ethical approval was sought and obtained from the Social Science, Humanities and Law Research Ethics Subcommittee (SSHL RESC), which forms a section of King's College London University ethics committee. Participants were informed that the author would be undertaking future research and were asked if they were willing to take part in a future study, if they met the inclusion criteria.

Setting

This study took place in four hospital outpatient clinics. The following information about the four clinics was collected using a contextual data collection sheet, which was distributed to a rheumatology consultant at each hospital (see APPENDIX 10).

Clinic A was the location from which the majority of the study sample was recruited (n=81). This was due to it being both the largest clinic and one in which the rheumatology consultant was particularly interested in the research. Clinic appointments were available for patients on three afternoons per week. The rheumatology clinic team consists of three healthcare professionals (HCPs) – the consultant, a rheumatology specialist nurse and a registrar. Patients who were prescribed osteoporosis medication were followed-up after 3 months and were given a 30 minute appointment with one of the HCPs.

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Clinic B was the first clinic which was enrolled to take part in this study. However, recruitment was slow at this clinic because many of the patients were prescribed zoledronate and were therefore not eligible. There were two consultants carrying out one clinic each per week, with up to eight patients being seen by each consultant. Patients were usually allocated 15 minutes appointments and were reviewed yearly. Twenty-five patients were recruited from this clinic. Since recruitment at this clinic was very slow, it was decided to advertise the study on the National Osteoporosis Society (NOS) website, so that clinicians could get in contact if the study was suitable for their clinic.

Clinic C had a consultant and a registrar each running one clinic per week, with up to eight patient appointments per session (usually three new patients and five follow ups). The consultant contacted the author and asked for the opportunity to take part in the study (through the advertisement on the NOS website). Patients are usually seen twice before discharge and they receive one or two follow-ups where medication adherence is reviewed. New patients are allotted a 30 minute consultation; follow-up patients were allotted 20 minutes. Patients are given the NOS drug treatment leaflet and many are referred to an exercise session with a strong educational component. Two patients were recruited from this clinic.

Clinic D had one consultant running one clinic per week; with up to 12 patients seen during each clinic (four new patients and eight follow-up). Patients' first appointments are usually 45 minutes, with one or two follow-ups lasting approximately 10 minutes. Patients on oral medications are being discharged to primary care where possible, while patients prescribed infusions are followed up at this trust yearly. The National Osteoporosis Society website leaflets are used to educate patients about adherence. Five patients were recruited from this clinic.

Recruitment

Two groups of patients were recruited for this study; those that attended their clinic appointments and those that did not attend their last appointment. To recruit

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attenders, osteoporosis clinics were visited on 41 different afternoons. Different recruitment processes were used across the clinics as follows:

- 1) In clinics A and D, the doctors invited their patients to take part in the study at the end of their consultation.
- 2) In clinics B and C, the author approached patients in the waiting room and invited them to participate. To protect confidentiality in the waiting room, patients were asked to read the inclusion criteria and to indicate whether they were eligible. If patients agreed to consider taking part, they were given the participant information sheet and were given the opportunity to ask questions. If they agreed they were asked to sign the consent form. If they wanted to talk further about the study I took them into a private room to protect confidentiality.

For non-attenders, secretaries from clinics A and B provided the author with the contact details for patients who had failed to attend their clinic appointments over the preceding six months. These patients were sent invitation letters and consent forms in the post to sign and return if they wanted to take part. Reminders were sent at three and six weeks after the questionnaires were initially sent out in order to enhance recruitment.

Each participant was given six questionnaires to complete (a demographic data collection sheet and the five questionnaire measures described above). The questionnaires took between 30 and 45 minutes to complete. If patients were unable to fill in the questionnaires themselves, e.g. due to problems with manual dexterity, yet still wanted to take part, the author administered the questionnaires as a structured interview and patients' responses were recorded for them. This took between 45 and 90 minutes. Patients were given the choice of completing the questionnaires in the waiting room or to take them home to complete and post back.

Questionnaires were administered in clinic waiting rooms, either before or after patients' consultations. To increase the response rate, patients were also given the

option of taking questionnaires home to complete if they were unable to spare the time at the clinic. A private room was available at each clinic in case patients wanted to discuss matters confidentially with the author. There were two recruitment periods for the study; between July and December 2011 and again between September 2012 and January 2013.

Overall, 170 sets of questionnaires were distributed by the author; 121 were returned (response rate = 71%) by the attenders (n=108) and non-attenders (n=13). For the attenders group, 141 questionnaires were distributed, with a response rate of 77%. Twenty-nine questionnaires were distributed to non-attending patients, 12 returned them with a response rate of 41%. Of the final 121 completed questionnaires, a proportion had to be excluded. In the attenders group, seven were excluded, two of whom had not completed over half of their questionnaires. A further five were excluded because they were prescribed only calcium or vitamin D for osteoporosis and had therefore completed the questionnaires in error. Two participants in the non-attenders group were excluded because they were prescribed calcium only. Exact details of the number of participants who declined to take part in the study are non-existent, as the clinic staff members assisting with the study were not able to keep records of the number of participants they invited due to their time constraints.

7.5 Analysis

Statistical analysis was carried out using IBM SPSS statistics version 18. Three main stages of data checking were carried out to ensure the database was correctly prepared for analysis.

- 1) The accuracy of the entered data was checked twice by the author. In addition, 10% of the data were checked for accuracy by an independent assessor.
- 2) Some questionnaire items required reverse scoring before the data were analysed. The SPSS function 'recode' was used to reverse score these items. Recoded variables were then manually checked to ensure that scores were reversed to the figures intended.

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- 3) After calculating mean scale scores using an SPSS syntax file, the total scores of the scales were manually calculated for five participants and the total compared with the SPSS database. This was carried out to further check that the data were entered correctly and to check that the SPSS syntax was correct. In addition, the independent assessor manually calculated each scale score for five different participants.

The distribution scores of each scale were assessed to check that they met the assumptions for parametric tests. All three adherence measures were substantially skewed; the MARS score was negatively skewed, while percentage non-adherence and total barriers were positively skewed. Logarithmic transformation (Log10) is recommended for data that are skewed (Ferketich & Verran, 1994). It is important to note that before performing log10 transformation, first the direction of the MARS data had to be reversed, to make it positively skewed so that it was suitable for log10 transformation. This had the effect of artificially reversing the direction of the relationships between the MARS score and the other study variables. Therefore, in the reported results, the direction of the relationships with the MARS score was reversed to reflect the direction of the original relationships.

To compare the predictive value of each theory, multiple linear regressions using the enter method were carried out to test both models (the extended SRM and the EPPM) separately in order to investigate the extent to which these models predicted self-reported adherence to medication for all three measures of adherence. These regressions were carried out to assess whether these variables explained the variance in adherence to medication.

Factor analysis was used to reduce the number of study variables, with the aim of building a more parsimonious model of osteoporosis medication adherence. A final multiple linear regression was carried out to investigate the relationship between the newly constructed factors and adherence to medication, as well as to investigate whether the new variables could explain the variance in adherence behaviour.

7.6 Results

7.6.1 What is the extent of non-adherence in this population of osteoporosis patients?

Based upon the Medication Adherence Report Scale (MARS), 26% of patients reported full adherence to their osteoporosis medication (with a score of 25/25). Using a MARS score of < 23 to signify non-adherence, 36% of the study participants were classified as non-adherent. Forty-six per cent of this sample reported missing at least one dose of their medication in the last month and 71% reported at least one barrier to taking their medication. The percentage of non-adherent patients for each MARS item is shown in Table 14. In congruence with other studies of adherence to medication, adherence scores were skewed (see Table 15).

Table 14. Percentage of non-adherent patients for each MARS item

MARS Item	Percentage of participants who reported sometimes, often or always for each item
I forget to take my medicines	22.5%
I alter the dose of my medicines	10.1%
I stop taking my medicines for a while every now and again	22%
I decided to miss out a dose	18.9%
I decided to take less than instructed	10.1%

Despite efforts to recruit patients who did not attend their clinic appointments, only 11 of the 112 participants included in the study were non-attenders. Considering the large difference in the numbers of participants in each group, it was decided to carry out a non-parametric test to compare scores for adherence between these two groups. The same was carried out to investigate differences for all the study scales between these two groups. The Mann Whitney U test showed that there was a significant difference in adherence between the groups for the MARS score ($U=299.00$; $p=.011$) and the percentage non-adherence score ($U=291.00$; $p=.027$). There

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was lower adherence in the non-attenders group. No significant differences were found for the number of barriers to adherence reported in each group, or for any of the psychological factors investigated.

7.6.2 Descriptive statistics and reliability analysis

Table 15. Descriptive statistics and reliability analysis for adherence measures (properties of multi-item scales)

Adherence measure	Mean Score	Range	Standard Deviation	Cronbach's Alpha	Number of Items	Skewness
MARS	4.41	1-5	.793	.886	5	-2.39
Percentage non-adherence	13.8	0-100	27.543	NA	1	2.30
Total barriers*	1.12	n/a	1.264	.518	6	1.194

*There was space for free text to record additional barriers on the total barriers questionnaire, so there was no limit to the number of barriers reported.

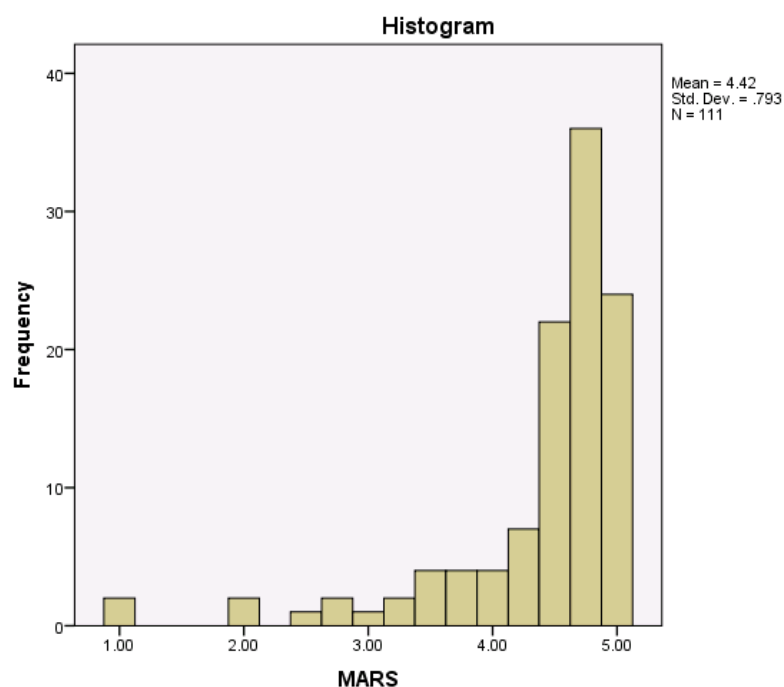


Figure 12. Distribution of adherence to medication in osteoporosis patients (MARS scores)

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Correlations between each of the three measures of adherence are shown below (Table 16).

Table 16. Correlation analysis between the three measures of adherence

	MARS	The number of missed doses (percentage non-adherence)
The number of missed doses (percentage non-adherence)	-.601**	-
Total Barriers	-.590**	.375**

Note;**<.001

In each following section, study data from each model is presented in turn (extended SRM and EPPM). Firstly reliability analysis for each scale is displayed, as well as descriptive statistics (the distribution of scores in each scale). Secondly, correlation data are presented, followed by multiple linear regression data. Three multiple linear regressions were carried out for both models, to test the models for each adherence measure. The final section is factor analysis, with a multiple linear regression of the new overarching factors and adherence, again with each adherence measure.

Descriptive statistics and Cronbach's alpha for all the extended SRM scales (IPQ-R and BMQ) are shown in Table 17. The internal reliability of each scale was acceptable, with the exception of the IPQ-R Chance Attribution scale ($\alpha= 0.302$). Hence this scale was excluded from the analysis.

Table 17. Descriptive statistics and reliability analysis of IPQ-R and BMQ Scales

IPQ-R or BMQ Scale	Mean Score	Range	Standard Deviation	Cronbach's Alpha	Number of Items	Skewness
IPQ-R Osteoporosis symptoms	1.61	0-21	2.425	N/A*	15 (+4 Optional items)	3.045
IPQ-R General symptoms	6.91	0-21	4.630	.855	"	.345
IPQ-R Medication related symptoms	.675	0-21	1.681	N/A*	"	5.509
IPQ-R Psychological Attribution	2.02	1-5	.748	.895	6	.427
IPQ-R Risk Factor Attribution	2.52	1-5	.634	.669	7	.140
IPQ-R Immune Attributions	2.17	1-5	.731	.689	3	.004
IPQ-R Chance Attributions	2.34	1-5	.834	.302	2	.071

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IPQ-R or BMQ Scale	Mean Score	Range	Standard Deviation	Cronbach's Alpha	Number of Items	Skewness
IPQ-R Timeline (Chronic)	3.73	1-5	.696	.797	4	-.319
IPQ-R Consequences	2.49	1-5	.756	.787	6	.289
IPQ-R Personal Control	3.53	1-5	.683	.836	6	-.269
IPQ-R Treatment Control	3.43	1-5	.585	.651	5	.150
IPQ-R Cyclical Timeline	2.56	1-5	.771	.697	3	.154
IPQ-R Emotions	2.61	1-5	.947	.902	6	.201
IPQ-R Coherence	3.64	1-5	.788	.885	5	-.414
BMQ Necessity	3.08	1-5	.638	.730	5	.176
BMQ Concerns	2.52	1-5	.722	.712	5	.333

*These scores contained a large number of zeros, making it impossible to perform a test of internal consistency.

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Descriptive statistics and Cronbach's alpha for all EPPM scales are shown in Table 18. The internal reliability of each scale was acceptable, with the exception of the RPQ severity scale ($\alpha = 0.387$). Therefore the severity scale was excluded from the analysis. It is expected that the low alpha was due to a low understanding that osteoporosis is a fatal disease, because while on average people agreed that osteoporosis was a serious disease (mean=3.98, SD=.763), it appears that they did not agree that it can be a fatal disease (mean=2.67, SD=1.090). All RPQ Scales were normally distributed.

Table 18. RPQ Descriptive statistics and reliability analysis of RPQ scales

RPQ Scale	Mean Score	Range	Standard Deviation	Cronbach's Alpha	Number of Items	Skewness
Severity	3.32	1-5	.740	.387	2	0.63
Susceptibility	3.88	1-5	.616	.658	2	-.469
Medication Efficacy	3.33	1-5	.793	.743	2	-.694
Self-efficacy	3.70	1-5	.904	.834	2	-.965
Emotions	3.10	1-5	.928	.870	2	-.230
Motivation	4.37	1-5	.619	NA	1	-.434

7.6.3 Socio-demographic and clinical Factors

Correlation analysis was carried out in order to determine if any of the socio-demographic or clinical factors were associated with medication adherence. Of all the demographic and clinical factors investigated only one small significant relationship was found. Age was negatively correlated with total barriers ($r=-.213$; $p<.05$), thus as age increased, the number of barriers to adherence reported decreased. No other relationships were detected for clinical or socio-demographic factors and adherence.

While there were no significant relationships between the two BMQ scales (necessity and concerns), there were many relationships between IPQ-R scales, which are shown in the table below. As shown in

Table 19, the majority of correlations between IPQ-R variables were as expected. For example there were strong positive correlations between: personal control and treatment control; emotions and perceived consequences and identity with perceived consequences. There were strong negative correlations between coherence and consequences, which means that as coherence increases, perceived consequences decrease. There was a negative relationship between personal control and psychological attributions, so that as personal control increased, psychological attributions decreased.

7.6.4 Correlation analysis

Table 19. Correlations between IPQ-R variables

Scales ⁵	1	2	3	4	5	6	7	8	9	10	11	12
2	.414**											
3	.684**	.215										
4	.386**	.319**	.247*									
5	.152	.118	.015	.443**								
6	.289**	.340**	.179	.660**	.370**							
7	-.036	.024	-.105	-.049	-.088	-.108						
8	.408**	.447**	.116	.394**	.156	.443**	.129					

⁵ Note; * $<.05$; ** $<.001$; Key for scales; 1. Osteoporosis symptoms; 2. General symptoms; 3. Medication related symptoms; 4. Psychological attribution; 5. Risk factor attribution; 6. Immune attribution; 7. Timeline (acute); 8. Consequences; 9. Personal control; 10. Treatment control; 11. Coherence; 12. Timeline (cyclical); 13. Emotions

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Scales ⁵	1	2	3	4	5	6	7	8	9	10	11	12
9	-.109	-.161	.034	-.217*	.133	-.353**	-.198*	-.187*				
10	-.131	-.164	-.025	-.184	-.066	-.230*	.485**	.296**	.565**			
11	-.204	.254**	-.150	-.176	.081	.270**	.188	-.172	.376**	.312**		
12	.317**	.373**	.037	.313**	.037	.501**	-.038	.508**	-.106	-.021	-.277**	
13	.350**	.459**	.233*	.474**	.264**	.359**	.084	.755**	-.106	-.234*	-.187	.413**

Note; *<.05; **<.001; Key for scales; 1. Osteoporosis symptoms; 2. General symptoms; 3. Medication related symptoms; 4. Psychological attribution; 5. Risk factor attribution; 6. Immune attribution; 7. Timeline (acute); 8. Consequences; 9. Personal control; 10. Treatment control; 11. Coherence; 12. Timeline (cyclical); 13. Emotions

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Few IPQ-R variables were significantly correlated with self-reported adherence (see Table 20). There was a positive relationship between perceived negative consequences and the total barriers reported, so that as the consequences of osteoporosis increased, more barriers to taking medication were reported. Similarly a positive relationship between personal control and percentage non-adherence was found, being that as belief in personal control increased, non-adherence increased. As the emotional responses to having osteoporosis increased, more barriers to adherence were reported.

The relationship between the two BMQ scales (necessity and concerns) was not significant (see APPENDIX 20). A significant relationship was detected between concerns about medication and two of the adherence measures; MARS and total barriers. The necessity scale did not correlate with any measures of adherence, though it correlates with: IPQ emotions ($r=.282$; $p<.001$); susceptibility ($r=.367$; $p<.001$) and coherence ($r=.222$; $p<.05$). The concerns about medication scale was significantly associated with many other scales in the study, for example, as concerns about medication increased, the emotional response increased ($r=.562$; $p<.05$).

Correlations between all the scales measured in the study and each adherence measure are shown in Table 20. Motivation, self-efficacy and concerns about medication had the strongest associations with osteoporosis medication adherence. Correlations between all scales used in the study can be found in APPENDIX 20.

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Table 20. Correlations between all scales and measures of adherence

	Medication Adherence Report Scale (MARS)	Missed doses (percentage non- adherence)	Total Barriers
Identity (number of osteoporosis symptoms)	NS	NS	NS
Number of symptoms in general	NS	NS	NS
Number of medication related symptoms	NS	NS	NS
Psychological Attribution	NS	NS	NS
Risk Factor Attribution	-.199*	NS	.245*
Timeline (Chronic)	NS	NS	NS
Timeline (Cyclical)	NS	NS	NS
Consequences	NS	NS	NS
Personal Control	NS	.233*	NS
Treatment Control	NS	NS	NS
Coherence	NS	NS	NS
Emotions (IPQ)	NS	NS	NS
Necessity	NS	NS	NS
Concerns	-.336**	NS	.387**
Perceived Susceptibility	NS	NS	NS
Self-efficacy	.415**	-.299**	-.554**
Medication-efficacy	NS	NS	NS

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	Medication Adherence Report Scale (MARS)	Missed doses (percentage non-adherence)	Total Barriers
Emotions (RPQ)	NS	NS	.196*
Motivation	.432**	-.333**	-.321**

Note; * $<.05$; ** $<.001$; NS=not significant

Adherence was significantly associated with motivation (for all 3 measures of adherence). The direction of the relationship is that as motivation increases, adherence increases. The concerns about medication score was associated with both the MARS and the total barriers scores, but not with percentage non-adherence. The data indicates that as concerns about medication increase, non-adherence increases.

7.6.5 To what extent can adherence be predicted by the extended SRM?

Multiple regression analysis was used to test if the extended SRM scales (IPQ-R and BMQ) significantly predicted participants' adherence as measured using their MARS scores. The results of the regression indicated the predictor variable explained 11% of the variance in adherence to medication ($r^2 = .116$, $F=2.291$; $p=.013$). It was found that concerns about medication significantly predicted the MARS score ($\beta=.446$; $p=0.000$). Women were less likely to adhere to their medication as their concerns about medication increased.

Similarly, multiple regression analysis was used to test if the extended SRM scales (IPQ-R and BMQ) significantly predicted participants' adherence as measured using their 'percentage non-adherence' scores. This did not produce a significant model ($r^2 = .036$; NS).

Finally, multiple regression analysis was used again to test if the extended SRM scales (IPQ-R and BMQ) significantly predicted the score on the total barriers questionnaire. The results of the regression indicated the predictor variable explained 15% of the variance in adherence to medication ($r^2 = .145$, $F=2.821$; $p=.006$). It was found that concerns about medication significantly predicted the 'total barriers' to adherence ($\beta=.472$; $p=0.000$), so that as concerns about medication increased, the number of

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barriers to medication also increased. See Table 21 for a summary of the variance in each measure of adherence explained by the extended SRM.

Table 21. Summary of the variance in adherence explained by the extended SRM

Adherence Measure	R²	F	P	% Variance explained
MARS	.116	2.291	.013	11
%non-adherence	-	-	NS	-
Total Barriers	.145	2.821	.006	15

7.6.6 Can adherence be predicted by the EPPM?

Multiple regression analysis was used to test if the RPQ scales significantly predicted the MARS score. The results of the regression indicated that two predictors explained 28% of the variance ($r^2=.276$, $F=9.127$, $p=.000$). It was found that self-efficacy predicted MARS score ($\beta=-.312$, $p=.000$), as did motivation ($\beta=-.393$, $p=.000$).

Multiple regression analysis was used to test if the RPQ scales significantly predicted participants self-reported percentage non-adherence. The results of the regression indicated the two predictors explained 13% of the variance ($r^2=.134$, $F=4.069$, $p=.002$). It was found that self-efficacy significantly predicted percentage non-adherence ($\beta=-.237$, $p=.003$) as did motivation ($\beta=-.307$, $p=.004$).

Multiple regression analysis was used to test if the RPQ scales significantly predicted participants' total barriers scores. The results of the regression indicated that the RPQ scales significantly explained 34% of the variance in total barriers ($r^2=.343$, $F=11.751$, $p=.000$). It was found that self-efficacy significantly predicted total barriers ($\beta=-.491$, $p=.000$), as did motivation ($\beta=-.237$, $p=.009$). See Table 22 for a summary of the variance in each measure of adherence explained by the EPPM.

Table 22. Summary of the variance in adherence explained by EPPM

Adherence Measure	R²	F	P	% Variance explained
MARS	.276	9.127	.000	28
%non-adherence	.134	4.069	.002	13
Total Barriers	.343	11.751	.000	34

7.6.7 To what extent does a combination of the extended SRM and the EPPM explain adherence?

Due to the large number of predictor variables investigated in the study and the strong correlations between many of the variables, an exploratory factor analysis was used to explore the possibility of reducing the number of variables, with an aim to formulate a more parsimonious model to explain the study data. 'The primary purpose of exploratory factor analysis is to arrive at a more parsimonious conceptual understanding of a set of measured variables by determining the number and nature of common factors needed to account for the pattern of correlations among the measured variables' (Fabrigar et al, 1999, p274). Factor analysis was used in the present study to explore whether two models could be combined to explain adherence.

Since there were many correlations between the psychological factors investigated in the study (see APPENDIX 20), it was hypothesised that it was possible to identify a smaller number of higher order factors that could be tested for their ability to predict adherence. An examination of the Kaiser-Meyer Olkin measure of sampling suggested that the sample was factorable (KMO=.598). Barlett's test of sphericity was significant ($\chi^2 (426) = 78, p = .000$). These tests indicate that the data were factorable and the sample size was acceptable for exploratory factor analysis (De Winter et al, 2009).

The 'scree test' was used to determine the number of higher order factors (Cattell, 1966). The scree plot (Figure 13) demonstrates that there are four factors above 1 Eigenvalue, which denotes a four factor solution. A four factor solution means there

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are four over-arching factors which can be identified as possible adherence predictor variables (Figure 13).

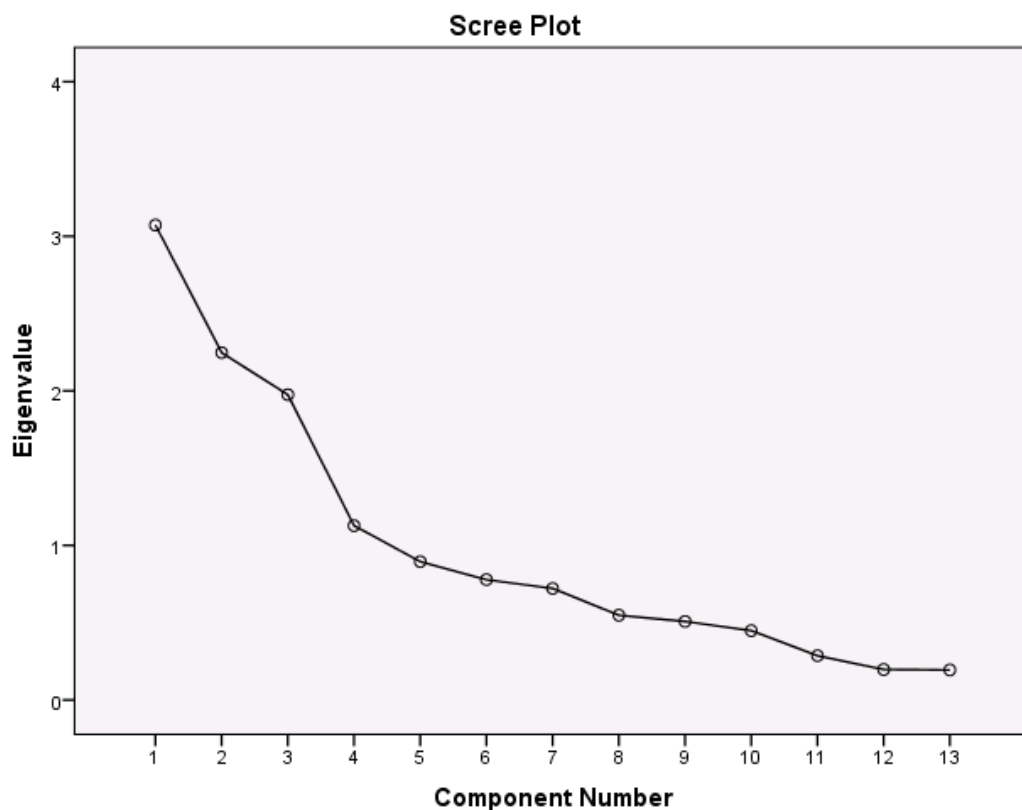


Figure 13. Scree plot indicating a four factor solution

A principal components analysis with a promax (oblique) rotation of 13 scales was conducted. Oblique rotation is required when there are many correlations among the scales being analysed (Hendrickson & White, 1964). The severity and chance attribution scales were excluded from the exploratory factor analysis due to low reliability. Further, identity and the other three causal attribution scales were also excluded because they were dichotomous scales and were therefore too dissimilar to all the others to be included in the factor analysis.

After inspection of the variables loading on each of the factors, they were named: Emotional responses, controllability, understanding and motivation. Table 23 shows the factors which load on the four main factors. These factors explained 68% of the variance. Theoretically the factor loadings are logical.

7.6.8 A possible model of adherence

Four scales loaded onto factor one, named *emotional responses*. The Eigen value showed that the first factor explained 24% of the variance. These scales indicate an emotional response to having osteoporosis, e.g. concerns about the medication could lead to a strong emotional response.

Perceived control was the name assigned to factor two, on which three scales loaded. This factor explained 17% of the variance. It is clear from Table 23 that these three scales all related to the extent to which patients feel osteoporosis can be controlled, by them or by medication.

The four scales that load onto factor three relate to patients *perceived understanding* of their condition. For example, this factor includes their understanding of the condition, or their need for medication. This factor explained 15% of the variance.

Two scales loaded onto factor four, self-efficacy and motivation. Given that self-efficacy is theorised to be required for motivation, factor four was labelled 'motivation.' Motivation explained 8% of the variance. Although motivation loads slightly higher on factor three, theoretically it belongs on factor four with self-efficacy rather than on factor three, which is about understanding.

Table 23. Factor loadings and communalities based on a principle components analysis with oblique rotation for 15 scales from the extended self-regulation model and the extended parallel process model

Scales	Factor 1 Emotional Responses	Factor 2 Perceived Control	Factor 3 Perceived Understanding	Factor 4 Motivation
IPQ Timeline		-.569	.517	
IPQ Consequences	.894			

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Scales	Factor 1 Emotional Responses	Factor 2 Perceived Control	Factor 3 Perceived Understanding	Factor 4 Motivation
IPQ Personal Control		.694		
IPQ Treatment Control		.860		
IPQ Cyclical Timeline	.754			
IPQ Emotions	.791			
IPQ Coherence	-.393		.590	
BMQ Necessity	.428		.569	
BMQ Concerns	.362			-.648
RPQ Susceptibility			.752	
RPQ Medication Efficacy		.781		
RPQ Self-efficacy				.894
RPQ Motivation			.571	.424

Note. Factor loadings < .3 are suppressed

7.6.9 Multiple linear regression

The four newly identified factors (which are referred to as the new combined model) were regressed with each of the three measures of adherence. Multiple regression analysis was used to test if the new model significantly predicted the MARS score. The results of the regression indicated the predictor variable explained 29% of the variance ($r^2=.290$, $F=11.128$, $p=.000$). Motivation was the significant predictor of the MARS score ($\beta=-.570$, $p=.000$).

Multiple regression analysis was used to test if the new combined model significantly predicted percentage non-adherence. The results of the regression indicated the predictor variable explained 10% of the variance ($r^2=.104$, $F=3.645$, $p=.009$). Motivation was the significant predictor of percentage non-adherence ($\beta=-.380$, $p=.000$).

Multiple regression analysis was used to test if the new combined model significantly predicted the total barriers score. The results of the regression indicated the predictor variable explained 35% of the variance ($r^2=.346$, $F=13.453$, $p=.000$). Motivation was the significant predictor of the total barriers score ($\beta=-.606$, $p=.000$). See Table 24 for a summary of the variance in each measure of adherence explained by the EPPM.

Table 24. Summary of the variance in adherence explained by a combination of the extended SRM and the EPPM

Adherence Measure	R ²	F	P	% Variance explained
MARS	.290	11.128	.000	29
%non-adherence	.104	3.645	.009	10
Total Barriers	.346	13.453	.000	35

7.7 Discussion

7.7.1 Key findings

Over three quarters of the study participants reported a degree of non-adherence with their osteoporosis medication recommendations. The study identified that patients have a range of beliefs about their condition, medication and risk (see Figure 41 to Figure 53). This study provides evidence that illness beliefs, treatment beliefs, emotional responses and risk perceptions are implicated in adherence behaviour. The study identified a possible new model of adherence to osteoporosis medication, consisting of four psychological factors; emotional responses, perceived control, perceived understanding and motivation. Motivation was the only significant predictor variable in the multivariate analysis (this consisted of a combination of the motivation and self-efficacy scales from the EPPM).

One of the valuable prospects of identifying psychological factors which are related to osteoporosis medication is that these factors may be amenable to psychological intervention. The study findings show empirical support for both the extended SRM and the EPPM; both were capable of explaining significant variance in adherence to osteoporosis medication. Self-efficacy and motivation were the strongest predictors of adherence. Concerns about medication were also a strong predictor of adherence. There is also support for a new model of adherence, consisting of a combination of psychological factors from both the extended SRM and the EPPM.

Consistent with extant findings, the low level of adherence detected in this population of patients was as predicted. For example, WHO estimate that up to 50% of patients do not take their medication as prescribed (WHO, 1994). It was not surprising that the majority of the clinical or social context factors measured were not related to osteoporosis medication adherence, as similar research for other medical conditions has produced congruent findings (Osterberg & Blaschke, 2005). The present study detected a small relationship between age and barriers to medication, so that as age increases, the number of barriers to taking osteoporosis medication decreased. An explanation for this relationship could be that adherence to medication becomes more important to individuals as they get older. This could be because with ageing, avoiding

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poor health outcomes becomes increasingly important (Myers & Midence, 1998). Another possible explanation is that many of the older people in the study were retired, perhaps giving them less competing demands on their time and organisation.

This was not the first study to compare two models in their prediction of health behaviour (Orbell et al, 2006). However, this was the first investigation of adherence to medication using the EPPM known to the author. It was also the first study to compare the EPPM and SRM known to the author. Based upon the amount of variance in adherence explained, the EPPM was superior to the extended SRM, for the MARS score, percentage non-adherence and total barriers. When both models were combined using exploratory factor analysis, they predicted 1% more of the variance in the MARS score and total barriers than either model alone. This provides some support for combining theoretical models. However, considering that correlations were modest and these models did not explain all the variance in the outcome scores, there are other factors which are not accounted for. It is likely that factors other than beliefs have an influence on adherence, such as doctor/patient relationship and communication, which were common themes identified in study 2 and in other previous research (Lau et al, 2008).

This was the first investigation of the relationship between the extended SRM variables and adherence to osteoporosis medication known to the author. As shown in research for other medical conditions (Hagger & Orbell, 2003; Hagger et al, 2006), the extended SRM was found to predict a small but significant amount of the variance in adherence, for both the MARS and the total barriers score. This shows that illness and emotional representations predict adherence, therefore changing these beliefs/emotions could result in some change in behaviour.

Many of the study findings replicate those of previous research. A key finding from the study was that motivation is a strong predictor of adherence. A large Italian study (n=9851) identified motivation, as well as side effects as predictors of adherence (Rossini et al, 2006). Given the evidence for motivation as a strong predictor, it would be beneficial to design an adherence intervention focussing on strengthening the

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motivation of osteoporosis patients, using motivational interviewing to help patients generate self-motivating statements about behaviour change (Rollnick and Miller, 1995).

Concerns about medication are well established predictors of non-adherence (Carr et al, 2006; IOF, 2006) and non-persistence (Schousboe et al, 2010) with osteoporosis medication using various measures of concerns. In the multivariate analysis, concerns about medication was the significant predictor variable. In contrast to existing findings in other medical conditions, perceived necessity for medication was not significantly associated with adherence in the present study, though this is in agreement with previous research with osteoporosis patients (Schousboe et al, 2010). Previous research has demonstrated that perceived medication efficacy predicts medication adherence (McHorney et al, 2007). Perhaps patients in the present study's population did not perceive a need for osteoporosis treatment because of its silent nature. It is expected that perceived necessity will be 'more influential in acute conditions, or those where the relationship between medication taking and symptomatic benefit is not apparent to the patient' (Horne, 1997; p173). It should be noted that in Schousboe et al's (2010) study, perceived necessity for medication was related to non-persistence, but not non-compliance.

The present study identified self-efficacy for using medication to be one of the strongest predictors of adherence. It is likely that the reason self-efficacy was highly correlated with adherence was because there are many difficulties/barriers associated with bisphosphonates/strontium ranelate which limit patient's adherence, e.g. fasting. The present study supports the previous findings of Schousboe et al (2010) regarding self-efficacy. Schousboe et al (2010) measured the impact of medication self-efficacy (belief in one's ability to use medication without difficulty) and found it to be associated with non-adherence. Therefore belief in one's ability to use medication without difficulty could be the focus of an intervention to promote adherence. A useful intervention to increase self-efficacy could be plan-setting using implementation interventions. This could help patients to overcome problems associated with planning how to take their medication around a fasting period.

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The finding that perceived susceptibility to fracture predicts adherence (Cline et al, 2005) was not supported in the present study. In the structured interview the author carried out with participants who were unable to complete the questionnaires by themselves, it became apparent that some patients knew that they had an increased risk of fractures. However, they did not want to agree to 'I feel I may get a fracture in the future' because they wanted to have positive perceptions of their health risks in the future and did not want to attract negativity. Perhaps the specific statement used to measure susceptibility should be reworded for future studies. However, it is difficult to word susceptibility in a way that does not imply a negative outcome.

The wide range of patients' beliefs about osteoporosis and the medication provides evidence for tailoring adherence interventions to meet osteoporosis patients' needs. A method for capturing these individual needs is to assess patients' barriers to adherence. In a recent systematic review, it was recommended that adherence studies should use an assessment of the barriers to adherence to collect information about medication taking (Nguyen et al, 2013). The present study involved the design of a questionnaire to assess these barriers; the DOTMQ. However, an issue to be considered is whether the DOTMQ is a measure of adherence or rather a predictor of adherence.

7.7.2 Limitations

An important point is that in many studies of adherence, the number of participants classified as non-adherent is often only a small percentage. This means that adherence is being investigated at one end of the scale, in which the majority of patients are adherent. With a larger sample, with more patients classified as non-adherent, we might observe different results with stronger relationships between psychological factors and adherence. Conclusions about the differences observed between attenders and non-attenders in adherence should be made with caution, considering the large difference in numbers between the two groups. Further, there were a large number of non-responders in the 'did not attend' group, so the data collected may not be representative of the entire group.

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There are other limitations relating to the sample size and the data collected. Various oral medications for the treatment of osteoporosis were investigated in the study, however, there were not sufficient numbers of patients prescribed each to test as to whether different psychological factors predicted adherence to each medication. There are various recommendations for the sample size required in order to carry out factor analysis. One author recommends that the sample size should have five participants for every factor investigated and that the minimum sample size should be 100 (Gorsuch, 1983). The present study met this criteria with 112 patients and a ratio of over 5:1 for each independent variable investigated.

The limitation of cross-sectional studies is that the direction of the relationship between variables cannot be determined, due to the use of only one data collection time point. Further, this was a retrospective study and patients were asked to recall how many doses they had missed in the last month, which means the data are likely to be influenced by memory bias and difficulties of recall. Using self-report as a measure of adherence could be considered a limitation. This is discussed in the general discussion chapter of this thesis (chapter 11). The 'barriers to adherence' questionnaire showed promise as a type of proxy measure of non-adherence, because it was significantly correlated with both the MARS and percentage non-adherence.

There are limitations associated with using theories to guide research, primarily that theories ultimately lead to the exclusion of variables which may be important predictors of adherence. In the present study, an attempt to overcome this limitation was the use of two theories. However, important factors known to be related to adherence were not investigated such as doctor/patient communication (Shu et al, 2009) or the role of habit (Philipps et al, 2008). This could explain why the theories were not able to explain more of the variance in adherence behaviour. While this is a limitation, it is a very difficult to design a study to investigate all the possible psychological predictors of adherence.

Some patients recorded their questionnaire responses before their medical consultation, whereas others completed the questionnaires after. Data were not

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collected as to whether the medical consultation was before or after participants completed their questionnaires, which may have impacted their questionnaire responses. For example, if a patient was told during their medical consultation that their bone mineral density had not improved, this new information could alter their perception of the medication, which may influence their beliefs of medication necessity. For future research, patients could be asked to record whether they had seen their consultant before or after completion of the questionnaire.

Only one questionnaire item was used to measure motivation. Participants were asked whether they agreed with 'I intend to take my osteoporosis medication as prescribed'. This is a limitation of the study and could be overcome perhaps by including a Likert scale to rate the following item; 'I feel motivated to take my osteoporosis medication as prescribed.'

7.7.3 Implications for the design of interventions to improve adherence to osteoporosis medication

The study provides evidence for using a combination of two theoretical models in the design of an intervention to promote adherence. Self-efficacy and motivation are important psychological factors significantly associated with adherence and could be targeted in a future intervention to promote adherence. It would be expected that increasing both motivation and self-efficacy would increase adherence to some extent. A motivational interviewing intervention would be ideal to draw on and this could strengthen patients' motivation for taking their prescribed medication. Further, a method of increasing self-efficacy for using medication is required.

Given that both the extended SRM and the EPPM were found to significantly predict adherence, it would be beneficial to develop and test an adherence intervention based on these models. An intervention based upon these models would not be expected to completely eradicate the problem of low adherence, because there are other non-modifiable factors which also relate to adherence e.g. age. However, the study findings suggest behaviour change interventions based on these models are likely to produce some increase in adherence.

7.8 Conclusions and next steps

The present study enabled the identification of the theoretical predictors of adherence, thus providing an evidence-base for the design of an intervention to increase adherence to osteoporosis medication. Psychological factors from both the extended SRM and the EPPM significantly predicted adherence to osteoporosis medication. The significant predictors of adherence to osteoporosis medication from these models were:

- ❖ Concerns about medication
- ❖ Motivation
- ❖ Self-efficacy

When the scales for the extended SRM and the EPPM were factor analysed, a potential new model of adherence was formed. This new combined model significantly predicted adherence to medication; with four psychological factors:

- ❖ Emotional responses
- ❖ Perceived control
- ❖ Perceived understanding
- ❖ Motivation

Motivation and self-efficacy were consistent predictors of adherence across various measures of adherence. This study provides strong evidence that interventions to increase osteoporosis medication adherence should focus on these two factors. While some psychological predictors of adherence have been identified in the present study, there is no evidence base for the selection of specific intervention materials. Psychological theories are not easy to operationalize. Before designing a psychological intervention to promote adherence, intervention materials should be selected and tested. The following study demonstrates how images of osteoporosis were selected for inclusion in an information booklet about osteoporosis and its treatment.

8 Study 4: Osteoporosis patients' ratings of five visual images of osteoporosis

Chapter overview

This chapter presents a study that assessed osteoporosis patients' responses to visual images of osteoporosis. Firstly a brief background of risk communication is considered. Secondly, the role of visual images/pictures in health communication is provided. Thirdly, intervention studies that have used visual images in health communication will be reviewed, including a review of the use of visual images such as body scans to communicate health risks across various clinical settings. Finally the present study is described in which visual images were utilised to communicate risk to osteoporosis patients. Further the impact of these images on patients' cognitions, emotional responses and motivation to take their medication as prescribed is also discussed.

8.1 Introduction

Study 2 indicated that pictures of osteoporosis may be emotionally activating, indicating that visual representations of osteoporosis may have utility in adherence interventions, to inform patients of the effects of the condition and to motivate adherence. Harrow et al (2008) suggest that there is increasing interest in the relationship between visual representations of illness and the way in which physical images are used in health communication. However, the use of emotionally salient images needs to be carefully considered; negative emotions can motivate behaviour changes, but can also lead to avoidant responses if they lead patients to feel helpless (Witte, 1992). It may be particularly beneficial to use images to communicate risk in an asymptomatic condition such as osteoporosis where the patient experiences no concrete signs to indicate their illness condition.

As discussed previously, there is some evidence to suggest that osteoporosis patients do not understand their diagnoses or the risks associated with their condition (Giangregorio et al, 2009). Study 2 produced similar findings. This indicates a need for improved communication of risk in osteoporosis. Further there is evidence to suggest that osteoporosis patients experience difficulties in understanding risk information.

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Cadarette et al (2007) found that when osteoporosis patients were fed back the results of their Bone Mineral Density (BMD) scans, 61% of patients understood the numerical information presented in relation to their BMD, but 39% did not understand such information. Similarly Pickney & Arnason (2005) reported that 63% of people with a normal BMD reading correctly recalled the information. These findings are in accord with those of other risk communication researchers, who found that understanding of numerical risk information is low (Berry, 2004; Lipkus, 2007). Difficulties in understanding numerical risk information highlight a need for innovative methods of communicating the risk of fracture to osteoporosis patients.

Research has also focused upon the psychological impact of having a BMD scan. Rimes et al (1999) investigated the psychological and behavioural effects of having a BMD scan; they were interested in whether feeding back the BMD results to patients had any impact on osteoporosis preventative behaviours. Patients who were told that their BMD was low (which indicates they are likely to have or possibly develop osteoporosis) reported no increase in feelings of vulnerability but instead an increase in osteoporosis preventative behaviours. These findings suggest the potential use of a scan for prompting behaviour changes.

It is possible that BMD scans could be perceived as frightening by osteoporosis patients, as well as having other negative effects. The author of one study reported that BMD scans caused patients to feel more fragile and fearful about mobilising due to the risk of fracture (Hvas et al, 2006). The authors conclude that 'technological information indicating increased risk for osteoporosis appears to leave most affected women more uncertain and restricted than they used to be'(p2730). Although Hvas et al (2006) found their scans were not effective for communicating risk to osteoporosis patients', their study findings should be treated with caution for a number of reasons. Both the type of information which was given to patients in relation to their scan as well as the method for identifying their risk perceptions were not reported. The design was cross-sectional and so was not appropriate for identifying causal processes. Patients had received bone scans somewhere between one and three years prior to the study and were not shown the scans. The study therefore investigated the

patients' experience of having a bone scan rather interpreting their response to the information included on their scan. The challenge in any health communication is to inform individuals of their risk, but without causing them to be immobilised by the fear of such risks. Therefore it is important to be guided by theory when implementing health communication messages, so that any negative effects can be minimised. The author of the extended parallel process model (chapter 3) proposes that health threat messages (e.g. pictures of a medical condition) should only be presented to patients if they are combined with messages about what can be done to manage the risk (Witte, 1992).

8.2 Pictures in health communication

Risk communication is difficult because the information being conveyed is inexact (Berry, 2004). However, the way in which risk is communicated for diseases which are preventable / manageable is of great importance because it may influence subsequent behaviour. The use of images/pictures could contribute to a clearer way of communicating risk because 'non lexical visual information is often the first cue to signal a threat' (Bradley & Lang, 1999, p2). These authors argue that pictures are beneficial, particularly in healthcare because they activate cognitions and emotions and provide information which is concrete as opposed to abstract. There is strong evidence from a literature review to suggest that the use of pictures can enhance health communication (Houts et al, 2006). This review shows evidence from empirical studies that using visual images in health communication can improve the following: attention, comprehension, recall and adherence. Details of the way in which pictures have been useful in health communication and behaviour change interventions, will be discussed below.

The use of images may be effective in risk communication because images can target a wider audience than text, including those with literacy problems and non-English speakers (Houts et al, 2006). Further, images are predicted to be more influential than other types of risk communication because images can be processed unconsciously (Horowitz, 1970), which means they are less likely to be filtered out through conscious

thought processes. This is the reason that visual images are so commonly used in advertising. It is suggested that images can have their effect through subliminal influences on; emotions, beliefs and cognitions (Harrow et al, 2008; Williams & Cameron, 2009). If pictures can have a subliminal influence on health behaviour through advertising, it is worth exploring their influence in risk communication to promote healthy behaviours.

The vividness of visual images used in a message has been found to be an important predictor of the message persuasiveness. Vividness was only effective in changing health behaviour when it was coupled with a high efficacy message about what can be done to minimise the health threat (Block and Keller, 1997). Careful selection of a visual image for use in a health behaviour change intervention is therefore important because not all types of images will be effective.

8.2.1 Using visual images to change health behaviour

The use of visual images (pictures) to convey a health risk in osteoporosis is innovative and has the potential to improve adherence. Hollands et al (2010) conducted a Cochrane review of studies which investigated the use of visual images as a motivator for health behaviour change, studies utilised the method of showing patients their body scans and subsequently explaining them. The use of body scans is based upon the assumption that showing a patient a depiction of what their condition is doing to their body will motivate them to take action to improve it. There were mixed results as to whether using images can motivate health related behaviour. This highlights the need for future work to explore the utility of body scans in risk communication. It may be that body scans are difficult for patients to interpret.

There are some studies that suggest the use of images can be effective in changing health behaviour. The majority of research investigating the use of images in risk communication has focused on smoking cessation, with positive findings, e.g. a pilot intervention carried out by Shahab et al (2007) aimed to increase participants' intentions to quit smoking using images. Participants in the intervention group were presented with ultrasound images of their clogged up arteries. The intervention group

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perceived that they were more susceptible to smoking related diseases and were more likely to participate in smoking cessation behaviours post-intervention than the control group. This study demonstrated the effectiveness of images to help patients better understand their risk of disease which can subsequently lead to changes in health behaviour.

It is possible that images can have a negative effect on individuals. There has been much debate about the usefulness of picture warnings on cigarette packets (Ruiter & Gok 2005; Hammond 2006). For example, Hammond suggested that the pictures on cigarette packs are frightening and when not accompanied by any information for how to deal with the risk, the target individual is likely to ignore such picture warnings (Hammond, 2006). It is difficult to establish whether the images on cigarette packets are effective in promoting behaviour change.

Health messages using images often rely on eliciting fear and this has brought about a debate in the research literature regarding the benefits of fear appeals (Benet et al, 1993). Although there is evidence that fear appeals can bring about behaviour change, their use raises ethical concerns. However, considering that behaviour change is very difficult to encourage, it is plausible that some degree of fear is needed. It is important that the fear elicited is coupled with a motivational message of what can be done to minimise the health threat (Witte, 1992). This implies that an intervention using images to change health behaviour should be designed so that visual images are coupled with information about how to address the problem and therefore how to alleviate fear.

Aside from the potential to elicit fear, a further problem with the use of images/pictures in risk communication is that substituting verbal or written information with visual images could lead to some of the valuable information being lost. There are no guarantees that pictures will be interpreted in the manner required and that the risks will be consistently understood by all. It is important that pictures are accompanied by an explanation in order to tailor it to the needs of the individual.

Based upon the finding that not all types of image are beneficial in changing health related behaviour, it is important that any pictures selected for use in health / risk communication are carefully chosen and theory-based, in order to achieve effective communication and avoid any harmful effects associated with inappropriate use of pictures (Williams & Cameron, 2009). With a lack of theory-based studies for the use of visual images in health communication, there is a clear need for further research to look at what elements of a visual image are effective in influencing health behaviour.

8.2.2 Research using body scans in osteoporosis

Medical images of the body such as magnetic resonance imaging (MRI) scans and BMD scans have been investigated for their effectiveness for the communication of risk in several studies. The use of body scans to communicate risk to osteoporosis patients has been investigated (Cram et al, 2006; Estok et al, 2007) and allows for a very personal method to communicate risk to a patient, as they are presented with an image of their own body.

A randomised trial was carried out, in which osteoporosis patients in the intervention group were sent their BMD scans to inform them of the progression of their illness (Cram et al, 2006). The effect of this information on initiation of osteoporosis medication and satisfaction with osteoporosis care was assessed. Although more patients in the intervention group had initiated their medication for osteoporosis, the results were not significant. On a positive note, patients' satisfaction with their care increased.

Estok et al (2007) looked at whether showing patients their body scans would influence their calcium intake and physical activity regimes. In this randomised controlled trial, patients were assessed at baseline and at 2 time points post-intervention. At baseline, knowledge about osteoporosis predicted calcium intake and exercise levels. The authors noted a significant increase in calcium intake, but not in physical activity.

Neither study involved the use of a theoretical framework to decide how to present the body scans, making it difficult to understand the reasons for success/failure in

motivating behaviour change. While studies have investigated the impact of body scans on osteoporosis patients, none have examined whether other images, such as drawings of bones or pictures of people with osteoporosis can influence health behaviour.

8.3 Summary of the use of visual images in behaviour change interventions

It may be argued by some clinicians that presenting a patient with a visual image of the diseased area of the body is frightening and the concern is that it might be more harmful than beneficial. A Cochrane review of literature which assessed the impact of showing patients medical images of their own bodies demonstrated that the negative effects of this type of intervention are rarely explicitly measured (Hollands et al, 2010). It is important to investigate how patients respond to visual images, before employing them as intervention materials.

Overall, there is mixed evidence as to whether visual images of medical conditions can improve the communication of risk. While some studies support this idea (Shahab et al, 2007; Harrow et al, 2008; Hollands et al, 2010) others suggest that visual images do not significantly improve health behaviour (Cram et al, 2006). It is difficult to draw conclusions based on previous research and more controlled studies in this area are needed which employ theory to design and test interventions that use visual images in risk communication.

In study 2 it was observed that when patients were asked directly about their emotional responses to having osteoporosis, they reported a low emotional impact. However, when the patients were asked about how their drawings of osteoporosis made them feel, they described emotions such as anger and fear. Osteoporosis patients could benefit from new ways of having their fracture risks communicated to them, as this could help patients self-manage their condition, as well as facilitate understanding of information related to osteoporosis.

The rationale for the present study was to investigate the potential of visual materials for an adherence intervention. A set of images were rated in terms of how they

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impacted on osteoporosis patients': anger, worry, motivation, confidence, depression and fear. One aspect of the study was to investigate the potential benefit of visual images for future interventions which aim to help patients understand their illness and motivate behaviour change.

Research Questions

- How do osteoporosis patients respond to visual images of osteoporosis?
- Are there different responses to various images of osteoporosis?

8.4 Method

8.4.1 Measure

The Osteoporosis Images Questionnaire (OIQ) (see APPENDIX 21)

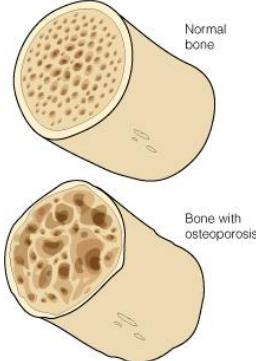
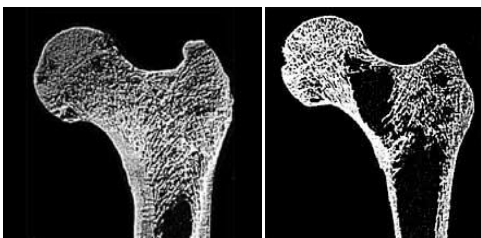
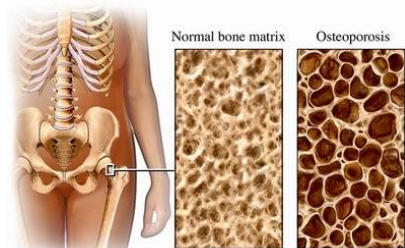
The OIQ was designed by the author for this study, to examine the responses of osteoporosis patients, when viewing images of osteoporosis. There were five images, each with nine related questions and five point Likert-scales to record responses. The nine questions were repeated for each image, each question formed a scale: frightened, informed, angered, motivated, depressed, confident, worried, confident that medication can help and helpless. The higher the score, the more positive or negative the reported response. There was also a free text box following each image for patients to record any comments about the image.

The images included in the questionnaire were selected by the author and then shown to two expert patients to explore whether they felt they would be suitable for inclusion in an intervention. The five images were selected to reflect slightly different elements of the damage which can occur to the body in osteoporosis. A range of different images was selected to assess whether their effects would be different and whether it would be possible to tailor the choice of image to each individual. Four of the five images were of bones both with and without osteoporosis and had varying levels of detail. Two of the images were of hip bones and three were cross-sections of bones. One image was a drawing of osteoporosis by a participant from study 2. One image was of a person who developed kyphosis. Examples of the images used are

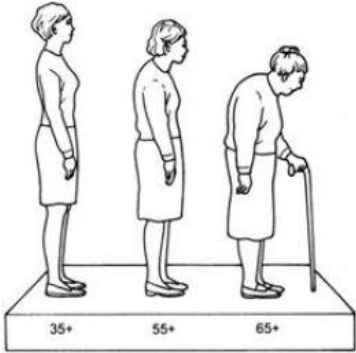
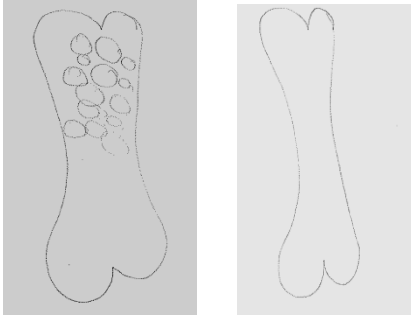
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shown below in Table 25. The nine questions were designed by the author and supervisory team and were based upon two themes, positive and negative effects.

Table 25. The images tested as potential intervention materials

Image	Images of osteoporosis
A	 <p>Normal bone</p> <p>Bone with osteoporosis</p>
B	
C	 <p>Normal bone matrix</p> <p>Osteoporosis</p>

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Image	Images of osteoporosis
D	
E	

8.4.2 Procedure

The participants were the same sample (n=112) as in study 3, (see the previous chapter for their demographic and clinical information). One hundred of these participants were included in the analysis of study 3. One participant did not complete the OIQ because she said she would find the images pessimistic.

The OIQ was distributed with the batch of questionnaires in study 3. The procedure was detailed in the previous chapter. Participants were given a questionnaire containing five images (shown in Table 25), which they were then asked to rate. There were nine statements about the influence of the images. For each image patients were asked to rate the effect it had on them. For each image, patients were asked to rate them with the following: 'when I look at this picture I feel...: frightened, informed, angered, motivated, depression, confident, worried, confident that medication can

help and helpless. There was a free text box after each statement for patients to add any additional comments about the images.

8.4.3 Analysis

In cases where more than two questionnaire items were missing (for one of the images), the participant's data was excluded from the analysis of that particular image (n=2). To determine whether participants' scores changed significantly across the different images, the Friedman test was used. The Friedman test is suitable to analyse the differences in responses to questions about each image, because the same questions were repeated for each image. For the qualitative data, participants' comments were coded as positive or negative, depending upon how they influenced participants. Correlation analysis was also carried out to investigate relationships between participants' responses to the images and all the scales in study 3 (IPQ-R, BMQ, RPQ and the three measures of adherence).

8.5 Results

Data for each stage of data analysis are presented in this section, including participants' qualitative and quantitative ratings of the images and the results of the correlation analysis. Ten participants did not complete the OIQ. The reasons for this are unknown, although questionnaires were distributed at the osteoporosis clinic, many participants took their questionnaires home to complete. Descriptive statistics are shown in Table 26.

8.5.1 How do osteoporosis patients respond to visual images of osteoporosis?

Table 26. Study 4 descriptive statistics

Image	Mean* Score	Standard Deviation	Cronbach's Alpha	Number of Items	Skewness
Frightened	3.43	.853	.897	5	-.527
Informed	3.74	.567	.804	5	-1.45
Angered	2.65	.787	.915	5	-.354
Motivated	3.99	.532	.868	5	-.640
Depressed	2.72	.856	.921	5	.128
Confident	3.70	.655	.944	5	-.687
Worried	3.15	.898	.923	5	-.400
Confident that medication can help	3.65	.614	.950	5	-.355
Helpless	1.83	.620	.899	5	.495

*Score range is 1-5, a high score indicates a high response

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Table 26 shows that the mean scores for each scale were higher for positively worded scales (e.g. informed, motivated) than for the negatively worded scales (e.g. depressed, helpless). The vast majority of participants did not complete the free text section of the questionnaires after each image. For those that did, there were mixed comments as to the influence of pictures on patients. Examples of participants' comments about the pictures are shown in Table 27.

Table 27. Participant's comments of 5 images/pictures of osteoporosis (A-E)

Image	Positive comments	Negative comments
A	<i>"Very useful in helping to understand the condition." (Participant 80)</i>	<i>"When I look at this image I am concerned." (Participant 38)</i>
B	<i>"Makes me realise that osteoporosis is a serious condition and that taking treatment is a must." (Participant 38)</i>	<i>"This image is more frightening than the first one." (participant 99)</i>
C	<i>"I can appreciate the fragility of bones with osteoporosis, it is a very good example." (Participant 67)</i>	<i>"This image is more frightening than the first one." (participant 99)</i>
D	<i>"My G.P told me taking risedronate would help to prevent dowagers hump - this is what motivated medication-taking." (Participant 20)</i>	<i>"I feel less good and less informed, as I have two aunts who looked like that and I assumed they had something else, e.g. ankylosing spondylitis" (Participant 18)</i>
E	<i>"Want to take action and medication on time." (Participant 69)</i>	<i>"This image is not helpful in any way. It conveys nothing, it is a bad drawing and suggests that this condition is not being taken too seriously." (Participant 80)</i>

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Image	Positive comments	Negative comments
General Comments	<i>"Images are helpful."</i> (Participant 32)	<i>"Anything I feel is completely removed from the pictures. A picture cannot make you feel anything."</i> (Participant 19)

8.5.2 Were there different responses to the various images of osteoporosis?

This section presents the results of the Friedman tests, which were carried out to investigate whether participants responded differently to each image. In cases where the Friedman test was significant, a Wilcoxon test was carried out to ascertain which image produced the strongest response.

Frightened

A Friedman test was conducted to evaluate differences between the median image ratings of fright: image A (median = 4), image B (median = 4), image C (median = 4), image D (median=4) and image E (median=3). The test was significant $\chi^2 (2, N =95) =30.288, p=.000$ and the Kendall's coefficient of concordance is .080.

Follow up pairwise comparisons were conducted using a Wilcoxon test. The median frightened rating was significantly greater for the following: image A was more frightening than image E ($p=.07$); image B was more frightening than image A ($p=.036$); image B was more frightening than image C ($p=.047$); and images B and D were both more frightening than image E ($p=.000$ for both). The median frightening ratings for all the other images did not differ significantly.

Informed

A Friedman test was conducted to evaluate differences between the median image ratings of feeling informed: image A (median=4), image B (median=4), image C (median=4), image D (median=4) and image E (median=4). No significant differences were found.

Angered

A Friedman test was conducted to evaluate differences between the median image ratings of anger: image A (median=3), image B (median=3), image C (median=3), image D (median=3) and image E (median=3). No significant differences were found.

Motivated

A Friedman test was conducted to evaluate differences between the median image ratings of motivation: image A (median=4), image B (median=4), image C (median=4), image D (median=4) and image E (median=4). The test was significant $\chi^2 (2, N =95) =14.302, p=.006$ and the Kendall's coefficient of concordance is .039.

Follow-up pairwise comparisons were conducted using a Wilcoxon test. The median motivation score was significantly greater for image D than image E, ($p=.010$), but the median motivation scores for images A, B and C did not differ significantly.

Depressed

A Friedman test was conducted to evaluate differences between the median image ratings of depression: image A (median=3), image B (median=3), image C (median=3), image D (median=3) and image E (median=3). No significant differences were found.

Confident

A Friedman test was conducted to evaluate differences between the median image ratings of confidence: image A (median=4), image B (median=4), image C (median=4), image D (median=4) and image E (median=4). No significant differences were found.

Worried

A Friedman test was conducted to evaluate differences between the median image ratings of worry: image A (median=3), for image B (median=4), image C (median=3), image D (median=4) and image E (median=3). No significant differences were found.

Confident that medication can help

A Friedman test was conducted to evaluate differences between the median image ratings of confidence that medication can help: image A (median=4), for image B

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(median=4), image C (median=4), image D (median=4) and image E (median=4). No significant differences were found.

Helpless

A Friedman test was conducted to evaluate differences between the median image ratings of helplessness: image A (median=2), for image B (median=2), image C (median=2), image D (median=2) and image E (median=2). No significant differences were found.

8.5.3 Were there any correlations between participants' image rating scores and their illness perceptions, medication beliefs, emotions, risk perceptions and adherence?

Correlation analysis was carried out to assess whether there were any relationships between the image ratings and adherence (as measured in study 3). Similarly the relationship between each image rating and the psychological factors investigated in study 3. For the majority of image rating scores, there were no significant relationships with any of the adherence measures. There were three small but significant relationships between image ratings and adherence. When ratings of depression increased, adherence decreased, for both the MARS score ($r=.198$; $p=.049$) and the number of missed doses ($r=.261$; $p=.012$). Similarly, individuals who rated the images as worrying had lower adherence ($r=.215$; $p=.038$).

There were very few correlations between the image rating scores and the psychological factors measured with the IPQ-R, BMQ and RPQ in study 3. As ratings of confidence increased, IPQ-R personal control increased ($r=-.201$; $p=.045$). As BMQ necessity beliefs increased, ratings of depression decreased ($r=.213$; $p=.036$). There were no other significant relationships between ratings of images and the psychological factors measured in study 3.

8.6 Discussion

The study demonstrated the mixed effects images of osteoporosis can have on individuals. There is some evidence that osteoporosis patients differed significantly in their responses to each image. Further, the qualitative information suggests that

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different images did have different effects. Overall this provides an argument for tailoring the choice of image to each patient's needs. This study was worthwhile and overall participants did not agree that the images made them feel depressed, angry or helpless.

Participants had a wide range of responses to each image, demonstrated in the distribution of ratings for each image (see APPENDIX 23 for histograms of the distribution of ratings). When the mean ratings of each image were compared, a significant difference was noted for ratings of how frightening the images were. There was also a significant difference for motivation, where one image (a person with kyphosis) was rated as significantly more motivational than the others. This information of varying responses to images provides evidence for tailoring the choice of an educational image of osteoporosis for each individual participant.

The qualitative data also suggests that the same image can affect various participants differently. While some participants found the image worrying but informative, others did not perceive any helpful benefits. The finding that participants were affected differently by the same image provides evidence for tailoring images to individual needs. It is difficult to determine whether an image that is frightening is positive or negative; on one hand it may be detrimental to coping with the condition adequately, on the other hand, being frightened might be a cue to action to protect health.

It was hypothesised that drawings of stereotypical cartoon type bones patients created in their drawings of osteoporosis in study 2 might be beneficial intervention materials, aimed at helping patients to better understand their condition. The present study indicates that this was not the case. Qualitative analysis of free text indicated that a drawing of osteoporosis was viewed as a poor representation of the condition and did not help to improve knowledge. Further, the drawing was rated as less motivational than an image of kyphosis.

The OIQ might have provided a covert measure of how osteoporosis patients felt about their condition. The correlation analysis produced some important findings. When patients agreed that images of osteoporosis were depressing and worrying, they

were less likely to be adherent to their osteoporosis medication. This finding provides some support for Witte's extended parallel process model (Witte, 1992). If patients have strong negative emotional responses to osteoporosis, perhaps their energy is used to manage these emotions rather than to manage the condition.

Limitations

Almost ten per cent of participants did not complete the osteoporosis images questionnaire which might be explained by the questionnaire being administered as the last of a batch of six. However, for future studies it may be beneficial to shorten the OIQ. It could also be beneficial to use a Latin square design to vary the order of questions for each image and reduce order effects to make it feel less repetitive for participants.

8.7 Conclusion

The use of visual images to convey the details of fracture risk in osteoporosis is innovative and has the potential to improve adherence. To inform future interventions, it is important for intervention development studies to assess the impact of the intervention materials prior to their implementation. This is of particular importance when the intervention materials include potential ethical issues for consideration. There is evidence from the present study to suggest that different visual images produce varying reactions in individuals, in terms of how frightening or motivational they are. The implication of this is that tailoring medical images to the needs of the individual patient might be more beneficial than simply producing educational materials with a one size fits all approach. The following chapter presents a pilot behaviour change intervention to promote adherence to osteoporosis medication, which was based on the findings from studies 1-4.

9 Study 5: A multifaceted intervention to increase adherence to osteoporosis medication: a case-series approach^{6,7}

Study overview

The use of an N-of-1 case-series design to study adherence to medication is a novel method to investigate low adherence with osteoporosis medication. It is predicted that this method will provide new information about non-adherence to osteoporosis medication, as well as provide the opportunity to test and evaluate the interventions behaviour change techniques and theoretical basis for improving adherence to medication. The intervention was given the title: The Adherence To Osteoporosis Medication (ATOM) study. The design was multiple cases with multiple units of analysis. An overall objective of the ATOM intervention was to inform patients about their condition and medication. The ATOM intervention consisted of the following behaviour change techniques: tailored education, motivational interviewing, telephone follow-up and implementation intentions, which were evaluated using mixed-methods. The aim was to investigate whether the intervention changed osteoporosis patients' beliefs about their condition, medication and fracture risk and to promote adherence to medication. A further aim was to assess whether patients' drawings of osteoporosis changed after the intervention. This chapter will focus on the outcome evaluation of each participant's response to the intervention.

9.1 Introduction

It has been previously documented that improving adherence to medication may have a higher impact on population health than improvement in the chemical properties of medical treatments (Haynes et al, 2008). There have been many previous attempts to improve adherence to osteoporosis treatment, yet essentially they have lacked a theory-base and evaluation (Gleeson et al, 2009). The limitations of previous studies

⁶ Please find the ATOM intervention manual on the CD included in the back pocket of this thesis.

⁷ This study was presented at The Florence Nightingale School of Nursing and Midwifery annual conference, King's College London (Besser et al, 2013b)

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make it difficult to interpret and explain any changes in adherence behaviour. In an attempt to overcome the problems of previous research, an adherence intervention was designed based upon the MRC's framework for the design and evaluation of complex interventions, which recommends theory selection, testing and built in evaluation (Campbell et al, 2000; Craig et al, 2008).

In accordance with the MRC's framework, four intervention development studies were carried out before the intervention was designed. These were a critical review (study 1), a qualitative study (study 2) and two quantitative studies (studies 3 and 4). Overall these studies have shown that patients have many informational needs about their condition and medication which have not been met, as well as beliefs which are not in accord with current scientific evidence. Studies 2 and 3 indicated that the theories selected to design an adherence intervention were appropriate and they enabled the identification of erroneous beliefs held by patients about their osteoporosis and medication. Importantly, these studies indicate that psychological factors are likely to have some influence on adherence behaviour.

The previous studies presented in this thesis provide a description of the evidence for using two theories to inform the design and information to be included in an intervention to promote adherence to osteoporosis medication. Two theories were used in this intervention; the extended Self-Regulation Model (SRM) (Leventhal et al, 1997; Horne, 1997) and the Extended Parallel Process Model (EPPM) (Witte, 1992). These theories define both a) the psychological constructs which should be targeted in the intervention and b) how intervention messages should be framed. The potential of these models to inform effective interventions to improve adherence to osteoporosis medication has not previously been investigated.

Two theories are being used because each of them can add something beneficial. The empirical support for using the two models together came from study 3. When the scales included in the models were combined using factor analysis, the new scales predicted slightly more of the variance in adherence than either model alone. The EPPM adds information about the role of self-efficacy and how to shape/deliver a

health risk message. The extended SRM determines specific beliefs about the medical condition and medication which may require intervention, as well as showing the dynamic nature of an individual's lay model of their illness and how this adapts to new information.

9.1.1 N-of-1 Design

An N-of-1 design is similar to a case study, such as that used in clinical practice. A case study is defined as an 'intensive investigation of an individual client' (Kazdin, 1981, p184). It has been documented that the case study approach has been neglected within the field of health psychology and is at the bottom of the 'tool box' of research methods, when it has the potential to reveal a great deal about health behaviours (Radley & Chamberlain, 2001). The case study approach has the ability to reveal new information about the way in which osteoporosis patients take their medication, because it involves in-depth work with a small group of patients. This approach allows the inclusion of multiple repeated measures before, during and after the delivery of a behaviour change intervention, which would be very difficult with a larger sample size.

A case study design has been selected to test behavioural theory in an intervention to promote adherence. As well as being recommended in the MRC's framework for the design and evaluation of complex interventions (Craig et al, 2008), a case study is the most suitable approach for the following experimental conditions: 1) investigation of 'how' or 'why' research questions, 2) the investigator has limited control over the events, 3) the focus is on behaviour in a real life context (Yin, 2009). A further justification for adopting the case study approach to test behavioural theory is that the psychological theories being investigated propose relationships between an *individual's* thoughts and behaviour (Westmeyer, 2003). Therefore these theories are well suited to the study of individuals.

A case study or N-of-1 design can be used to assess the effectiveness of a behaviour change intervention. Sniehotta et al (2012) investigated the usefulness of the case study approach to determine the effectiveness of an intervention. The intervention was based on self-regulation theory, with an aim to promote walking in healthy and

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obese adults. Walking increased for some participants who received the intervention. It was concluded that this method was useful to test behavioural theory.

As far as the author is aware, to date there is only a single example of a previous adherence intervention for physical illness with an N-of-1 design. The intervention was designed to promote adherence to anti-retroviral medication for adolescents with AIDS (Gray et al, 2011). It consisted of behavioural family systems therapy and was delivered to four participants with low adherence. The intervention was successful in increasing adherence, reducing barriers to adherence and reducing viral load.

9.1.2 Rationale for the selected behaviour change techniques

An adherence intervention is regarded as complex because the target behaviour is difficult to change and to sustain and there are many factors known to influence adherence. Therefore a multifaceted intervention to promote adherence was selected, with various behaviour change techniques or components. All elements of the intervention were tailored to the needs of each individual.

The behaviour change techniques used to promote medication adherence in the present study were selected based upon the findings of the previous intervention development studies, as well as previously published research. The techniques which were selected were as follows: psycho-education, motivational interviewing, implementation intentions and telephone follow-up. As well being guided by the Information, Motivation and Behavioural skills (IMB) model (Fisher & Fisher, 1992), the rationale for the selection of each behaviour change technique was as follows.

Definitions of behaviour change techniques have been provided by Michie and colleagues, so that researchers can ensure to use a common language when designing and evaluating interventions to promote behaviour change (Michie et al, 2008). These are being used to define the behaviour change techniques utilised in the present study (please see Table 28).

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Table 28. Definitions of behaviour change techniques

Behaviour change technique label for this intervention	Technique	Definition
Psycho-education	Provide information about behaviour-health link	General information about behavioural risk, for example, susceptibility to poor health outcomes or mortality risk in relation to better behaviour
Prompt barrier identification	Prompt barrier identification	Identify barriers to the behaviour and plans ways to overcome them
Follow-up telephone calls	Use Follow-up prompts	Contacting the person again after the main part of the intervention is complete
Motivational Interviewing	Motivational Interviewing	Prompting the person to provide self-motivating statements and evaluations of their own behaviour to minimize resistance to change

Psycho-education: A tailored information booklet

- Osteoporosis patients have been found to have some misconceptions about their condition and medication (study 2; study 3). These can be addressed through the provision of information
- Images of osteoporosis were found to be informative and positive (study 4) and patients had a range of responses to images. Therefore the choice of image was tailored to each individual

Included in the tailored educational component of the intervention, patients were given the opportunity to ask any questions they had about their condition or

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medication. Patients were told that any questions which could not be answered by the author would be referred to their consultant rheumatologist, when the questions reached the limit of the author's knowledge of osteoporosis.

Motivational interviewing (MI)

- The assumption of MI is that behaviour change is more likely to happen if a patient is able to make their own decision as to whether to change their behaviour (Rollnick & Miller, 1995)
- Motivation was strongly correlated with adherence to osteoporosis medication (study 3)
- The use of MI produced a clinically relevant increase in osteoporosis patients' medication adherence (Solomon et al, 2010). While this intervention used both MI and education, it did not use the following behaviour change technique; implementation intentions

Implementation intentions (referred to as plan-setting)

- Self-efficacy was strongly correlated with adherence to medication (study 3). A technique for increasing self-efficacy for using medication is to use an if-then plan. An if-then plan allows a patient to set a routine for taking their medication, e.g. if it is 7am and I am in the kitchen, I am just about to do my ironing, then I will take my medication
- If-then plans were previously found to improve adherence to medication to prevent epileptic seizures (Brown et al, 2009) and stroke (O'Carroll et al, 2013)

Telephone follow-ups

- Telephone follow-ups are a well-established method of increasing adherence (McDonald et al, 2002)
- Telephone follow-ups provide an element of tailoring the intervention to the needs of the individual, for example a telephone follow-up can be used to check whether a patient understands the educational materials they were sent in the post

9.2 Aims

An overall aim for this study is to test theory on a small scale and evaluate its effects. The intervention is based on four theoretical and methodological principles; small scale development and testing based on the MRC framework for complex interventions (Craig et al, 2008), using theory to inform the development of interventions, tailoring interventions to fit the specific needs of patients and in-depth quantitative and qualitative evaluation. If there is evidence that the intervention is beneficial it can then be refined and implemented in future research.

The objectives of this study are as follows: 1) to find out whether a theory-based intervention can influence adherence 2) to investigate whether the intervention has any influence on illness perceptions, medication beliefs, risk perceptions and emotional responses to osteoporosis; 3) to determine which elements of the intervention are successful and unsuccessful and 4) to explore any changes in patients drawings of osteoporosis through comparison of pre- and post-intervention drawings.

Research Questions

- How does a (pilot) theory-based intervention impact adherence to medication?
- What is the impact of a theory-based intervention to improve adherence on illness perceptions, medication beliefs, risk perceptions and emotional responses to osteoporosis?
- Were there common trends between participants?
- How do osteoporosis patients draw a visual representation of their condition before and after the intervention?

9.3 Method

9.3.1 Research Design

The present study design was an N-of-1 design, with multiple case studies and multiple units of analysis. There were two units of analysis in this study; the individual patients and the intervention. During the intervention period, changes in patients'

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psychological variables from the extended SRM and the EPPM and adherence were recorded over four months at monthly intervals. Two baseline assessments were carried out prior to the intervention, with one assessment during the intervention and two after the intervention was complete. The assessment time points were as follows: time point one varied between three months and two years pre-intervention, time point two was two weeks prior to intervention, time point three was during the intervention, time point four was one to two weeks post-intervention. Time point five was one month post-intervention. A summary of the design is shown in Table 29. In addition to the quantitative assessments, patients were asked to draw how they visualised; (a) a bone with and a bone without osteoporosis and (b) a person with and a person with osteoporosis. Drawings were collected at two time points, pre- and post-intervention. The following tables demonstrate the timescale and the implementation of each intervention component for each participant.

Table 29. Summary of intervention assessment time points

Summary of intervention assessments	
Assessment	Time point
1	Baseline 1 ⁸
2	Baseline 2
3	After psycho-education
4	After MI & plan-setting
5	One month post-intervention

⁸ The baseline 1 data came from an earlier study (study 3).

9.3.2 Participants

The participants were a sub-set of the study 3 participants who were identified with low adherence to medication. Patients were classified with low adherence when their MARS score ≤ 22 . Their demographic and clinical information is presented in Table 30.

Table 30. Demographic and clinical factors information of studies 5 and 6 participants

Participant	Age	No. of fractures	No. of years with osteoporosis	No. of medical conditions	No. of prescribed medications
1	59	0	5	1	2
2	68	0	16	4	4
3	67	0	20+	7	1
4	61	7	3	2	1
5	78	1	14	1	2
6	58	0	5	1	2
7	57	0	2	2	2
8	69	0	15	2	3

Inclusion/exclusion criteria

All study 3 participants who were still prescribed an oral medication (bisphosphonates, raloxifene and strontium ranelate) for osteoporosis were invited to participate. All the patients who agreed to take part were prescribed with the same medication; Strontium Ranelate (SR). Participants who were on a drug holiday were excluded.

Recruitment

All the participants in study 3 whose MARS scores indicated low adherence (n=27) were telephoned to check their eligibility for the intervention. Some participants had

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their prescription discontinued by their doctor between study 3 and the present study and were therefore no longer suitable for inclusion. If participants were still eligible for the intervention they were invited to participate. If they wished to consider whether to take part, they were sent a participant information sheet and a consent form to return if they agreed. Participants were telephoned a week after they received the study information to check whether they wished to participate. In anticipation of difficult recruitment for a study of such long duration, it was decided to offer an incentive of a £10 M and S voucher. Reasons for study decline or exclusion are shown in Figure 14.

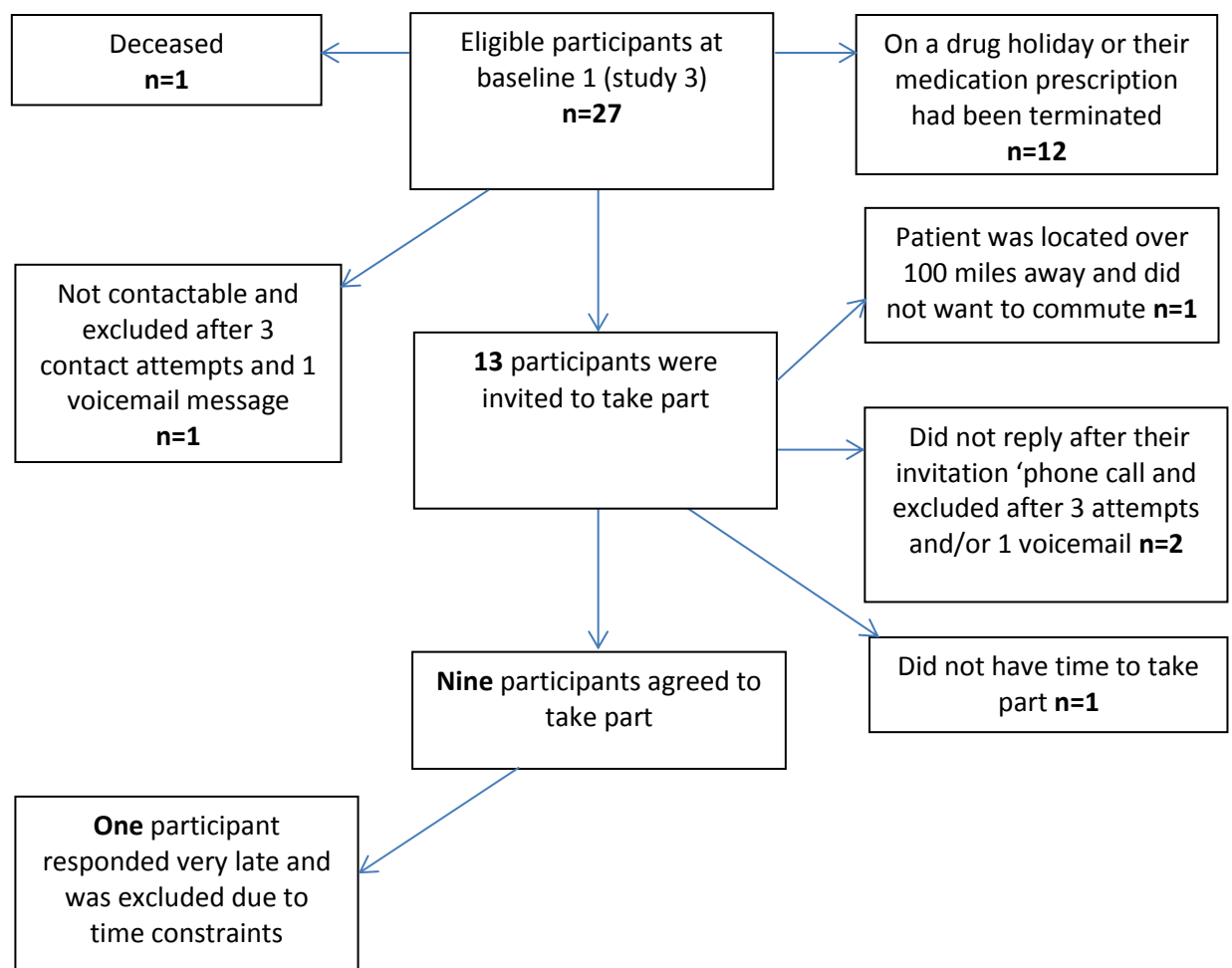


Figure 14. Reasons for intervention decline or study exclusion

9.3.3 Measures and Materials

The study 3 questionnaires provided the first baseline measure, pre-intervention. The assessment was repeated at four additional monthly intervals. To reduce participant burden and minimize attrition, it was decided that the questionnaires should be

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shortened. Both the IPQ-R and the BMQ were shortened from four to seven items per scale to two items per scale. This was carried out by inspecting Cronbach's alpha for each scale and item deletion statistics of the study 3 data. Those two items with the highest alphas were selected to form the measure for each scale. The individual items for each scale are shown in the intervention manual (please see the accompanying CD for the intervention manual).

The following primary outcomes measures were assessed:

- Illness perceptions and emotional representations⁹
- Medication beliefs¹⁰
- Risk perceptions¹¹
- Adherence to medication¹²
- Difficulties of taking osteoporosis medication¹³

9.4 Procedure

Each intervention component is briefly summarised below. The schedule used for the intervention components, length of each activity and the materials used is provided in Table 31. This is followed by an in-depth description of each intervention component including: the aim, delivery and content. A detailed description of the intervention and the intervention materials can be found in the intervention manual.

⁹ The 2 item per scale IPQ-R, adapted from the IPQ-R (Moss-Morris et al, 2002) shown in the interventional manual

¹⁰ The BMQ (Horne et al, 1999) shown in APPENDIX 13

¹¹ The RPQ (Turner et al 2008) shown in APPENDIX 15

¹² The MARS shown in APPENDIX 14

¹³ The DOTMQ shown in APPENDIX 16

9.4.1 Intervention summary

1. Psycho-education (delivered by post, telephone and face-to-face hospital session):

- Based upon each patient's questionnaire responses taken at baseline 2, a tailored information booklet was designed and posted to participants (details of how information was tailored is included in the intervention manual)
- The booklet includes a list of the benefits and barriers of taking osteoporosis medication
- In addition to the information booklet, patients were given the opportunity to ask any questions they had about their condition and/or medication during a follow-up 'phone call. Any questions which could not be answered by the author were referred to a medical specialist

2. Motivational interviewing(MI) (delivered during face-to-face hospital session):

- MI was used during the hospital session to help patients become aware of their motivation for taking their prescribed medication
- Some patients who were ambivalent to change were assisted to make a list to weigh up the benefits and barriers of taking osteoporosis medication.

3. Implementation intentions (plan-setting) (delivered during face-to-face hospital session):

- The hospital session included a section about the practical skills required to take medication as prescribed. This involved solving problems related to non-adherence, such as forgetting and routine setting
- After MI, patients who felt motivated to take their medication were assisted to devise a plan for how to take their medication as prescribed

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Table 31. Intervention schedule of assessment and intervention delivery

Timeline	Activity/assessment	Length of activity	Measures/Materials
This varied for each participant between 3 months and 2 years prior to the first week of the intervention	Baseline assessment 1	30-60 minutes	IPQ-R, BMQ, RPQ, DOTMQ
2-3 weeks prior to the first week of the intervention	Invitation 'phone call	5-10 minutes	-
1-2 weeks prior to the first week of the intervention	Follow-up invitation 'phone call to address participants questions about the study	10-20 minutes	-
Week 1	Baseline assessment 2	30-45 minutes	Two item per scale IPQ-R Two item per scale BMQ RPQ MARS DOTMQ Total Barriers Drawings
Week 2	Tailored information booklet was posted to participants	n/a	Information booklet tailored to the needs of the patient as assessed at baseline
Week 3	Follow-up educational 'phone call	30-45 minutes	Script provided in intervention manual
Week 4	Assessment 3	25-45	Two item per scale IPQ-R Two item per scale BMQ RPQ MARS
Weeks 5-6	MI and plan-setting session at hospital	1 hour in clinic	Script provided in intervention manual
Week 7	Follow-up motivational 'phone call	15-45 minutes	Script provided in intervention manual
Week 8	Assessment 4	25-45 minutes	Two item per scale IPQ-R Two item per scale BMQ RPQ

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Timeline	Activity/assessment	Length of activity	Measures/Materials
			MARS
Week 12	Assessment 5	15-45 minutes	Two item per scale IPQ-R Two item per scale BMQ RPQ MARS Total Barriers Drawings Topic guide for evaluation

9.4.2 Setting and delivery

The majority of the intervention assessments and delivery took place over the telephone or post, with one exception. The face-to-face session took place at the osteoporosis clinic. The intervention was delivered by the study author, who had been conducting research about adherence to osteoporosis medication for 3.5 years at the time of the ATOM intervention delivery. When required, the author was supervised by her academic supervisors and a medical specialist. The author had experience of teaching and motivational interviewing training at an introductory level. Assessments three, four and five were carried out by an independent assessor in order to blind the author to the outcome data and reduce the risk of social desirability bias. Participants were asked to agree the time and date for each intervention component, to ensure smooth delivery of the intervention.

The assessment of contextual data is an essential part of research using a case study design (Yin, 2009), because in-depth work with each patient allows time to collect a wealth of contextual data. The following demographic and clinical variables were ascertained at each baseline assessment and reassessed at the end of the intervention.

- Age of the patient
- number of years with osteoporosis
- number of fractures
- number of people co-habiting with

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- number of medical conditions
- number of prescribed medications

In order to tailor information to participants needs, their baseline questionnaire scores were used to diagnose whether they required information about a given psychological construct. For example, if they had a low perceived coherence score, they were given information targeted at improving coherence. A table of questionnaire scores which indicated the need for intervention was created, so that when patients' questionnaire response indicated low understanding, they would receive the appropriate information to address the low understanding (or misunderstanding). Therefore each participant received a slightly different information booklet, which omitted elements of the condition or medication for which they demonstrated good understanding. Full details of how information was tailored can be accessed in the intervention manual.

As well as tailoring the textual information about osteoporosis and medication, the images of osteoporosis selected for each booklet were also tailored. Information from participants' osteoporosis images questionnaires from study 4 were used to select the best images for each participant. Where possible the qualitative data was used to select an image, e.g. when a participant indicated that a particular image was informative or motivational they were provided with this preferred image. In the absence of qualitative data, images with the highest positive rating score were selected for the information booklet. In instances where more than one image had the same high positive score, images with the lowest negative score were used. In instances where there were multiple images with the same high positive and low negative score, the image with the highest range between high and low score were selected.

The intervention was delivered as intended to all but one participant, who did not receive two elements of the intervention due to factors beyond the control of the patient or researchers. Table 32 below shows the intervention components that each patient received.

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Table 32. Implementation of each intervention component

Participant	1	2	3	4	5	6	7	8
Tailored educational material	✓	✓	✓	✓	✓	✓	✓	✓
Image of osteoporosis	✓	✓	X	✓	✓	✓	✓	✓
Follow-up educational 'phone call	✓	✓	✓	✓	✓	✓	✓	✓
Questions noted	✓	✓	✓	✓	✓	✓	✓	✓
Decisional balance	N/A	N/A	✓	N/A	✓	N/A	✓	N/A
Exploring beliefs from assessment responses	✓	✓	✓	✓	✓	✓	✓	✓
Plan-setting	✓	✓	✓	✓	X	✓	✓	✓
Follow-up motivational 'phone call	✓	✓	X	✓	✓	✓	✓	✓
Questions answered	✓	✓	✓	✓	✓	✓	✓	✓

Note; N/A indicates that the element of the intervention was not intended for the participant

9.5 Analysis

The data were analysed using descriptive statistics. Differences were analysed within single cases, to look for changes in adherence to medication, beliefs, emotions, motivation and self-efficacy. Adherence was assessed in terms of mean level of change, trend (slope) and positive shift in terms of percentage adherence. This method is commonly used in single case designs (Kazdin, 2011). Qualitative thematic analysis of the intervention process evaluation interviews was also conducted and is discussed in the following chapter.

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The dependent variable was adherence to medication, which was assessed with three different self-report measures, the same as in study 3. The independent variables were: illness perceptions, medication beliefs, emotional responses, risk perceptions and patients' drawings. As mentioned previously, the scales used to measure the independent variables were shortened. Accordingly, baseline scores were calculated by selecting the shortened scales from the study 3 data for each patient.

Participants' drawings of osteoporosis were also analysed. Six participants completed two drawings; one of a bone with and without osteoporosis and one of a person with and without osteoporosis. The drawings were completed pre-and post-intervention. One participant refused to produce drawings. Another reported not knowing how to depict osteoporosis pre-intervention, but was able to complete a drawing post-intervention. To investigate what the drawings revealed about patients' thoughts about their illness, a thematic analysis was carried out, using the themes identified in the previous study of drawings of osteoporosis (study 2). Drawings of bones with and without osteoporosis were measured through their longest line and the results between each participant's pair of drawings were compared. Drawings were categorised for their similarities and differences, both within and between participants. In a validity exercise, a second researcher was asked to carry out a thematic analysis of the drawings. There was agreement between researchers in the themes identified.

9.6 Results

Firstly changes in adherence are presented. This is followed by a presentation of each case study, with scores for beliefs, emotions, risk perceptions, motivation and self-efficacy for each case. The participants are divided into two groups; four patients who had not initiated their prescribed medication at the outset of the study (group 1) and four patients who were taking their medication but with some difficulties (group 2). In group 1, 75% of patients initiated their strontium ranelate during the study. In group 2, all patients showed a slight increase in their adherence.

9.6.1 What is the impact of a (pilot) theory-based intervention on adherence to medication?

Prior to the presentation of the narratives for each case study, the data collected for each of the three measures of adherence are described. Following this the outcome evaluation data are presented (the process evaluation is in the following chapter). Table 33 below provides a comparison of the average MARS scores for all patients from baseline 1 until the final assessment. There was an increase in mean and median adherence scores, though no increase for the most common score.

Table 33. MARS scores over time for the whole sample

Time point	Mean	Median
1	3.17	3.50
2	2.65	3.90
3	2.90	3.70
4	3.63	4.50
5	3.53	4.60

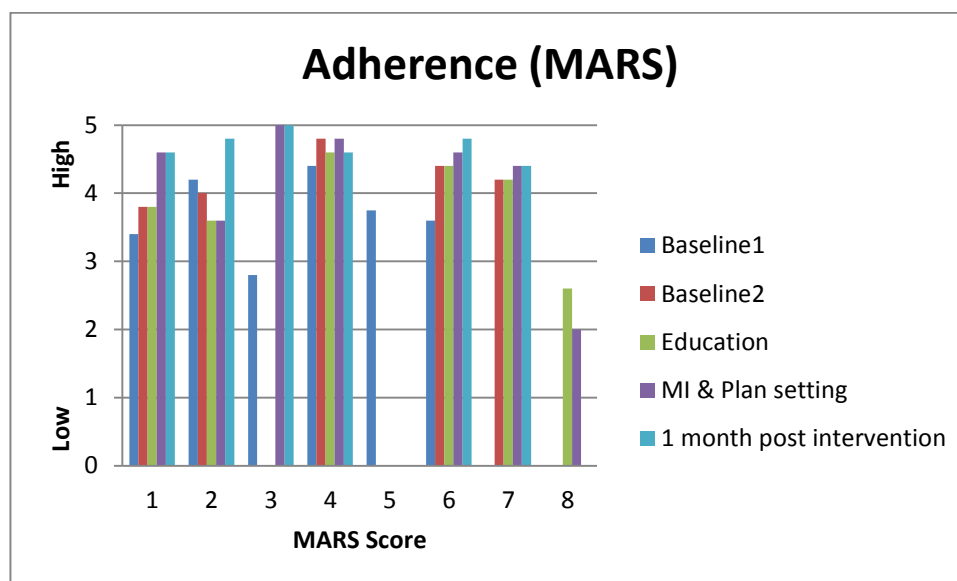


Figure 15. MARS scores for all participants pre-, during and post-intervention¹⁴

For the MARS score, all participants showed some increases in their adherence, with the exception of participant 5 (see Figure 15). Participant 8 started taking her medication after the education session. Improved adherence was also demonstrated by decreases in the percentage non-adherence score (see Figure 16). Where there is no score MARS score adherence, it indicates that patient was not taking their medication and was therefore exempt for answering questions about adherence.

¹⁴ Note: There are missing MARS scores for participants 3, 5, 7 and 8. Missing scores indicate that the participant was not taking their prescribed medication for a particular time point.

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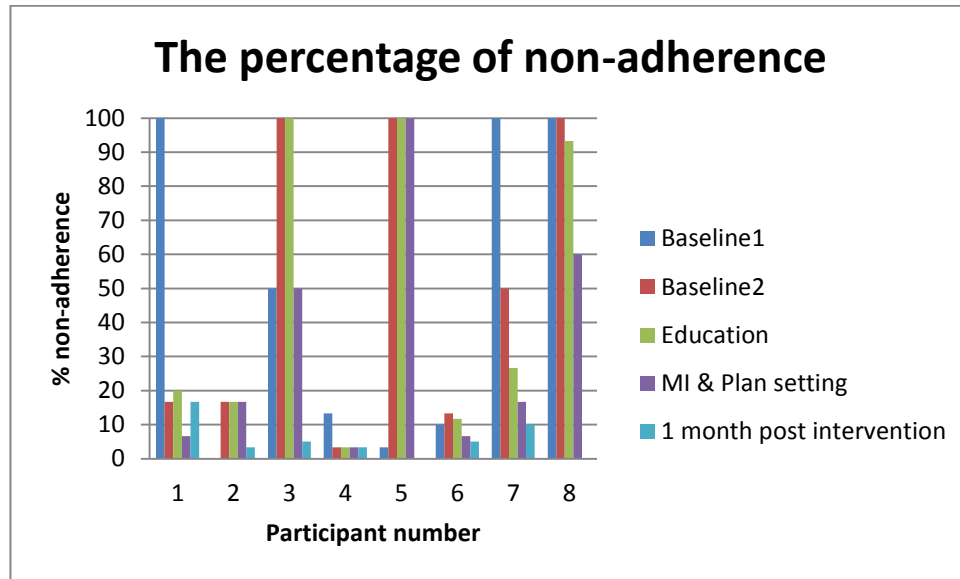


Figure 16. Percentage non-adherence; pre-, during and post-intervention

Figure 16 above demonstrates that between the pre- and post-intervention assessment percentage non-adherence decreased for all but one of the study participants (participant 5). Table 34 shows a decrease in the average percentage non-adherence for all participants, when their scores were grouped together.

Table 34. Changes in average percentage non-adherence scores over time

Time point	Mean	Median
1	47.08	31.7
2	50.00	33.3
3	46.46	23.3
4	32.50	16.7
5	30.42	7.5

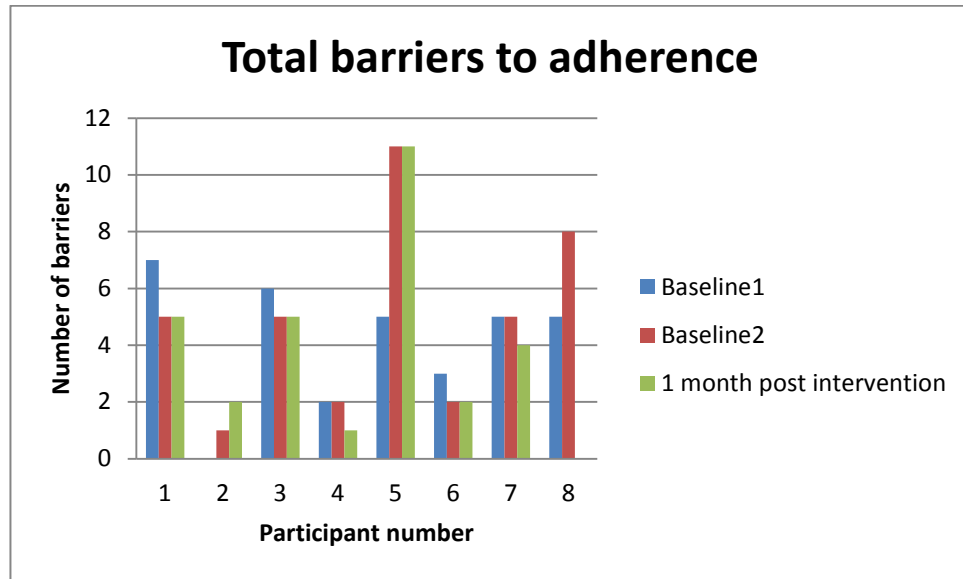


Figure 17. Changes in total barriers score pre-, during and post-intervention

While the average number of total barriers reported decreased (see Table 35), the graph above shows that only one participant reported fewer barriers to adherence post-intervention (participant 7). Many participants reported a decrease in barriers at baseline 2, before the intervention had commenced (see Figure 17). One reported more barriers at one month post-intervention than they reported at baseline 1.

Table 35. Changes in average total barriers to adherence scores over time

Time point	Mean	Median
1	4.13	5
2	4.88	5
5	3.17	3

9.6.2 What is the impact of a theory-based intervention to improve adherence on illness perceptions, medication beliefs, emotional responses and risk perceptions?

To examine changes within participants, data to demonstrate the changes in psychological factors for each individual case from baseline to one month post-intervention are presented below.

Group 1: Participants who were not taking their prescribed strontium ranelate at baseline

Participant 3

Participant three was a 67 year old woman who was diagnosed with osteoporosis over 20 years ago and had suffered no fractures. She was not in employment during the intervention. She said it was likely that her mother also had osteoporosis, though it was not diagnosed. As well as osteoporosis, participant 3 suffered from: chronic fatigue syndrome, chronic pain, irritable bowel syndrome, insomnia, anxiety and depression. She was not prescribed any medication other than SR. At baseline one she reported *"I am someone who finds it very difficult to take any kind of allopathic medication"* and listed five barriers to taking SR. There were two years between each baseline assessment.

While at baseline one she reported missing half of her doses of SR, by baseline two she was not taking any of the medication, reportedly because her care had moved to a new General Practitioner (G.P.) who had not yet prescribed it, even though it was recommended by her osteoporosis consultant. During the intervention period she re-initiated her SR.

During her MI session she reported that the motivation for wanting to take the SR was that she was getting older and that improving her bones might also improve other areas of her life. For her medication plan, she opted to take her medication sometime between 2 am and 6 am, since she often did not sleep well at night and this routine would not interfere with her daily meal times.

However, this participant had a markedly different experience during the intervention to the rest of the study participants. After saying she felt motivated to take her SR in her MI and plan-setting session, she was asked by her osteoporosis consultant to wait two weeks before re-initiating her medication, pending an announcement from the Medicines and Healthcare Products Regulatory Agency (MHRA) concerning the safety of SR. After the two week period, the osteoporosis consultant made an appointment to see participant 3 and recommended that the medication was safe for her to use.

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Due to this time lag it was decided that participant 3's second follow-up 'phone call would be omitted, given that it could not be delivered at the time it was planned for. Therefore it was not possible to review and amend her medication plan if necessary. Nonetheless, it appears that her adherence increased two weeks after her MI session (see Figure 15 and Figure 16). In the final assessment she reported that she was taking her SR, even though her G.P had advised against it.

In terms of illness perceptions (see Figure 18), her timeline score increased slightly, but only to a three which indicates unsure, rather than disagree. Two scores fluctuated with an overall increase: cyclical timeline and consequences. Her belief in the ability of the medication to control osteoporosis and her emotional response to the condition increased. Her coherence score increased after the intervention but decreased at one month post-intervention.

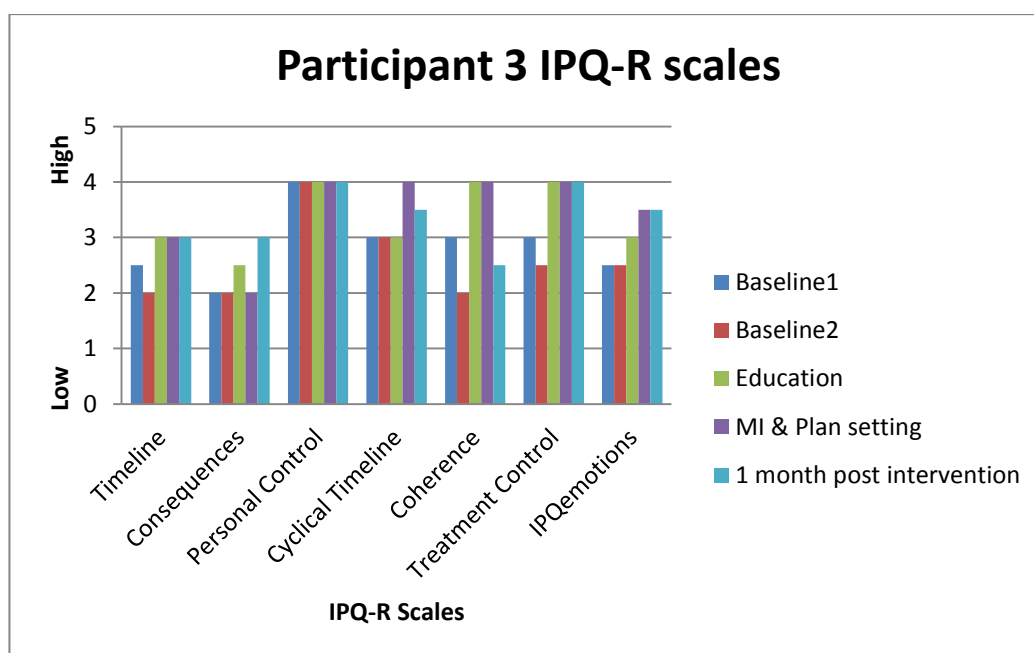


Figure 18. Participant 3: IPQ-R scale scores pre-, during and post-intervention

For medication beliefs, the patient's necessity beliefs increased after the MI session, though her concern beliefs fluctuated over the course of the intervention (see Figure 19). This fluctuation is not surprising given that half way through the intervention the

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patient was warned by her osteoporosis consultant that the medication may be unsafe for her to use.

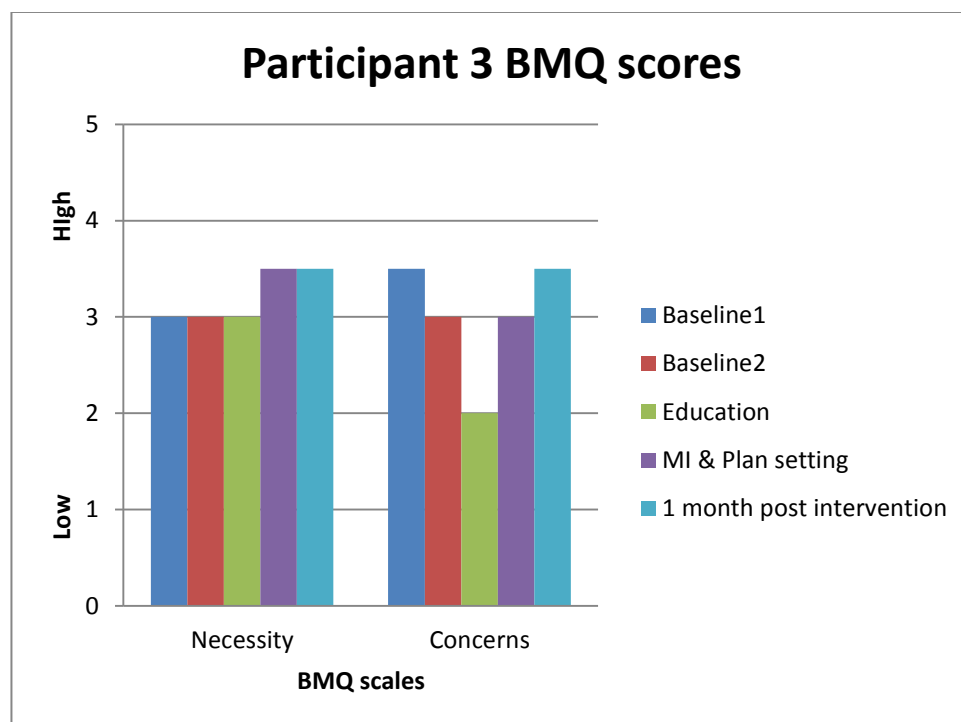


Figure 19. Participant 3: BMQ scales scores pre-, during and post-intervention

In contrast to the IPQ-R treatment control score, the patients RPQ medication efficacy score decreased slightly after the intervention. Her susceptibility score remained stable. Her self-efficacy and motivation showed a slight increase prior to the intervention. There was a slight increase in the RPQ measure of emotional response.

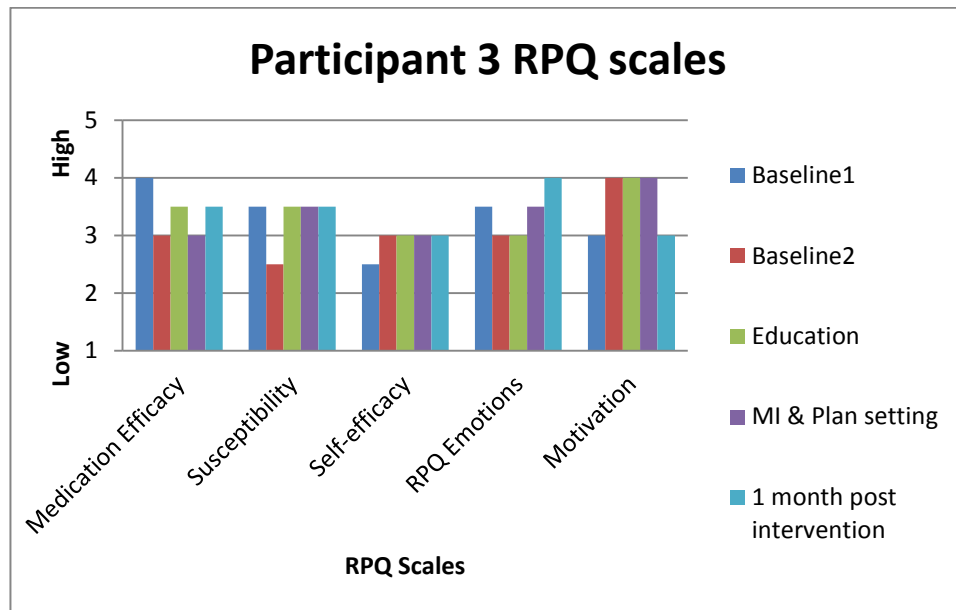


Figure 20. Participant 3: RPQ scale scores pre-, during and post-intervention

Participant 3 declined to complete the IOQ even though she completed the other questionnaires distributed in study 3. She said she would find the images of osteoporosis pessimistic and not in line with her way of thinking. Therefore it was not possible to provide this patient with a tailored image of osteoporosis in her information booklet. The patient was offered the opportunity to receive an untailored image and she also declined this offer.

Participant 3 also refused to create drawings of osteoporosis at both baseline and the final assessment. She reported that she did not want to create a negative image of osteoporosis. Although she refused to do the drawing, she explained what she would draw at baseline. She said she had recently seen a BMD scan and she would produce a drawing of a hip similar to her scan. She said for the normal bone, she would draw a clear bone and for the bone with osteoporosis, she would draw the damaged bits shaded. She said that she would not want to draw too much damage to the bone, because it conflicts with her way of thinking positively, although she is aware of the damage. For the drawings of people with osteoporosis, she said two images come to mind. One drawing of an elderly lady with a curved spine and one of a younger person for whom the disease is invisible, so there would be no difference between depictions of normal and osteoporotic people.

Participant 5

Participant 5 was the oldest participant in the study, aged 78. She had no family history of osteoporosis and had suffered one fracture prior to the study. She had suffered with osteoporosis for 14 years. Other than osteoporosis, she had two other medical conditions and was prescribed three medications in total. These were hypothyroidism for which she was prescribed thyroxin and glaucoma for which she was prescribed eye drops. She was prescribed SR and calcichew for her osteoporosis. At her first baseline she reported five barriers to taking the medication. She reported that her main barrier was the fasting period required which disrupted her social life, particularly now that she was retired and did not want to fast for a four hour period during the day. However, she was taking other protective measures to prevent fractures, including: daily exposure to sunlight for vitamin D, a calcium rich diet and a hip protector for long days out or if the weather conditions were unsafe. There were two years between each baseline assessment.

This participant's MARS score at baseline 1 was 19/25. Between baseline 1 and 2 she informed her doctor she had decided she no longer wanted to take her prescribed SR and her prescription was therefore terminated. It was difficult to decide whether to invite this patient to participate in the intervention, but she was included because her osteoporosis consultant said she could benefit from the intervention. This was because she had decided to discontinue the medication against her doctor's advice. Overall her decision to discontinue SR did not change during the study period. Between assessments three and five, the patient was told she had high cholesterol, which could mean that SR would no longer be appropriate for her.

The participant was ambivalent to re-initiate her medication, therefore decisional balance was used during her MI session. For every benefit she could identify with taking the medication, she could also list a barrier. While she recognised the importance of taking the medication, she said 'I know I should take it, but I can't'. When asked if there was anything that could help her to take this medication as prescribed, she said there was not, though she would take something else for it if that was possible.

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This participant showed an increase in perceived coherence of osteoporosis and a decrease in cyclical timeline (see Figure 21). This indicates she had a better understanding of osteoporosis post-intervention. Her personal control score increased at the baseline 2 assessment. Her emotional response to the condition remained low throughout the study. Her beliefs about treatment control and chronic timeline fluctuated during the study period.

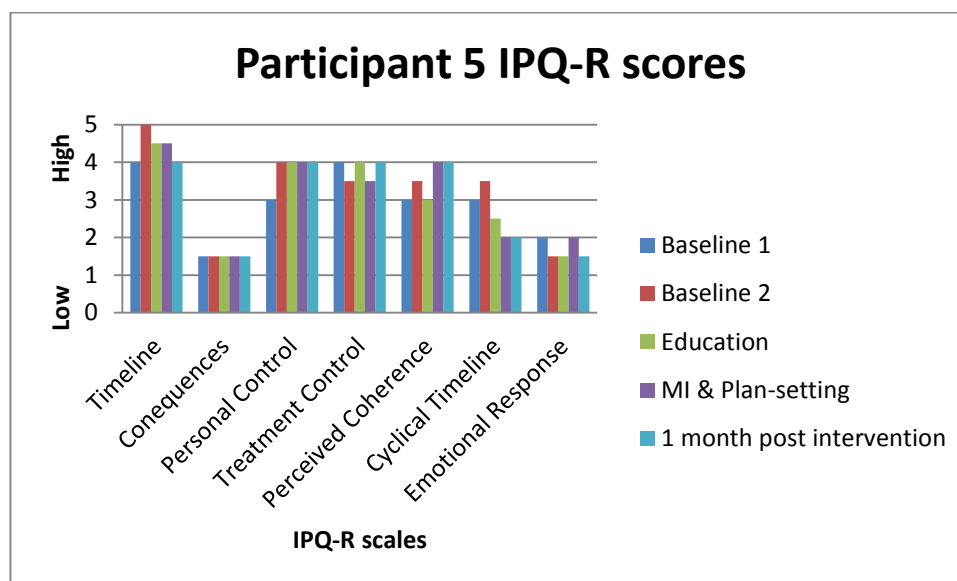


Figure 21. Participant 5: IPQ-R scale scores pre-, during and post-intervention

For medication beliefs, both necessity and concerns scores were low for this participant (see Figure 22). Concerns about medication slightly decreased between baseline 2 and the final assessment. BMQ scores were missing from this patient at the baseline 1 assessment.

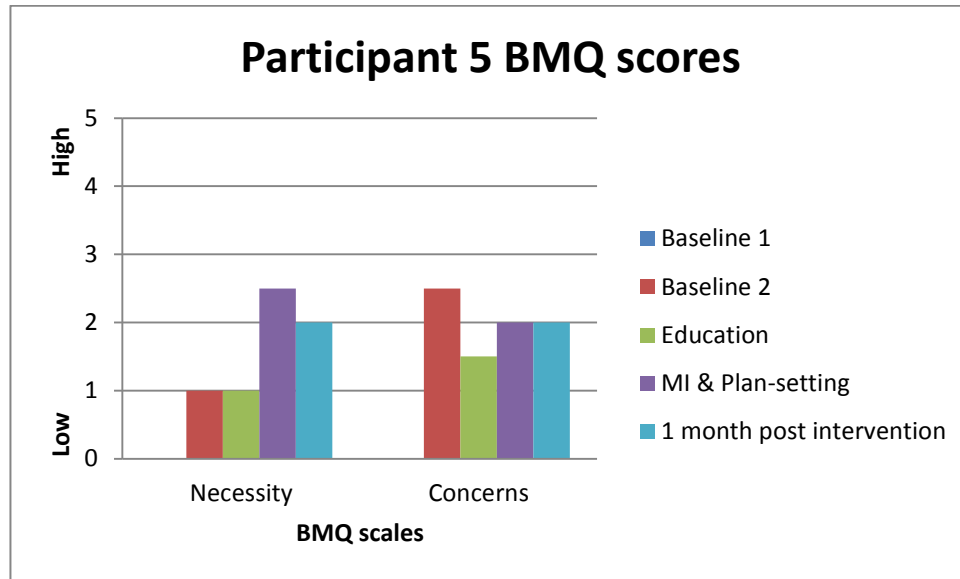


Figure 22. Participant 5: BMQ scale scores pre-, during and post-intervention

At baseline 2, participant 5 agreed that she was susceptible to fracture. However, post-intervention she was unsure about her susceptibility (see Figure 23). Even though she agreed that the medication can protect her against fractures, she had low self-efficacy for taking the medication. After her first assessment at baseline 1 she decided to discontinue her SR and the graph below shows that from baseline 2 she had low motivation for taking SR. Similar to the IPQ score, her emotional responses to having osteoporosis fluctuated but remained low throughout the study.

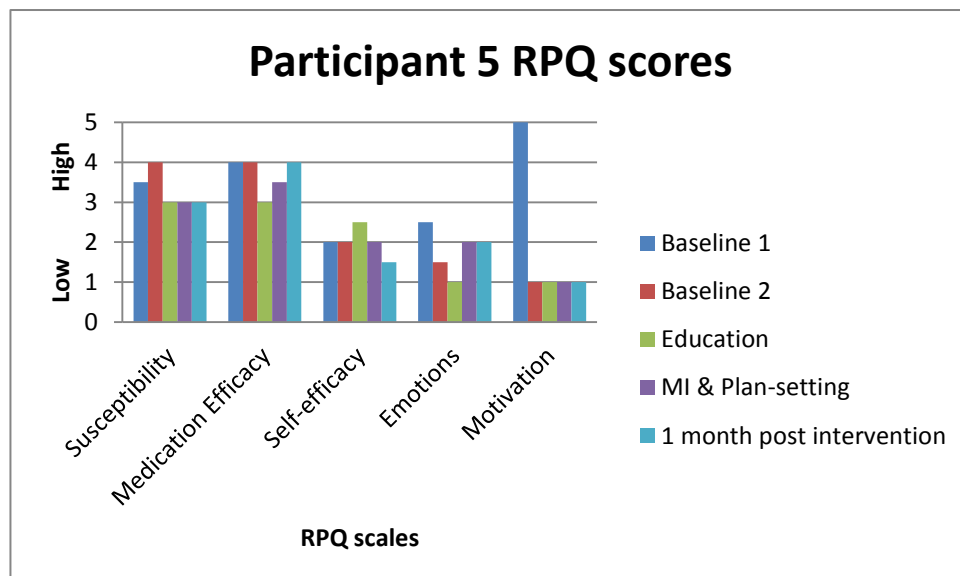


Figure 23. Participant 5: RPQ scale scores pre-, during and post-intervention

Participant 7

Participant 7 was a 57 year old woman who was diagnosed with osteoporosis two years prior to the study and had suffered no fractures. She was in full time employment. Both her mother and father were also diagnosed with osteoporosis. There were three months between her two baseline assessments. Other than osteoporosis, she was diagnosed with coeliac disease. As well as SR, she was prescribed vitamin D for osteoporosis. During her first baseline assessment, she reported that she was not taking the medication. In the free text box she wrote 'I can't see that the benefits outweigh the drawbacks.'

Participant 7 responded well to the intervention with an increase in MARS score (Figure 15) and a decrease in percentage non-adherence (Figure 16). At baseline 2 this patient reported that she had reinitiated her medication after she had received the 'phone call to be invited for the intervention. She said that over the two years she was prescribed with SR, she estimated having intermittently taken only three months of her doses in total.

Her motivation for taking the medication was to prevent fragility fractures, to build bones and prevent low quality of life. During the hospital session, she said she had a healthy scepticism towards SR. The author found it difficult to tell whether she was ambivalent about whether she should take her medication, so it was decided to offer the patient the opportunity to explore the benefits and barriers of SR, which she accepted. She welcomed the opportunity to make a plan for taking her medication. Her plan involved ensuring that she would eat her evening meal earlier in the evening, so that she had enough time to fast for two hours and to take the medication before going to bed. In her follow-up 'phone call she said she needed to make some amendments to her plan because it was difficult to implement on evenings when she attended seminars, when she would end up having to eat late. Therefore a different plan was made to enable her to take her medication on an evening when she would be going out to a seminar. She said she would take her medication at 8.30 pm, during the seminar and that therefore she was free to eat up until 6.30pm before the seminar and again after 10.30 pm on these nights.

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Many of participant 7's IPQ-R scores increased during the intervention and then reverted to the baseline 1 score by the final assessment (Figure 24). This was true for cyclical timeline, perceived negative consequences and the emotional response. Perceived coherence made a large increase, as did beliefs in treatment control and personal control.

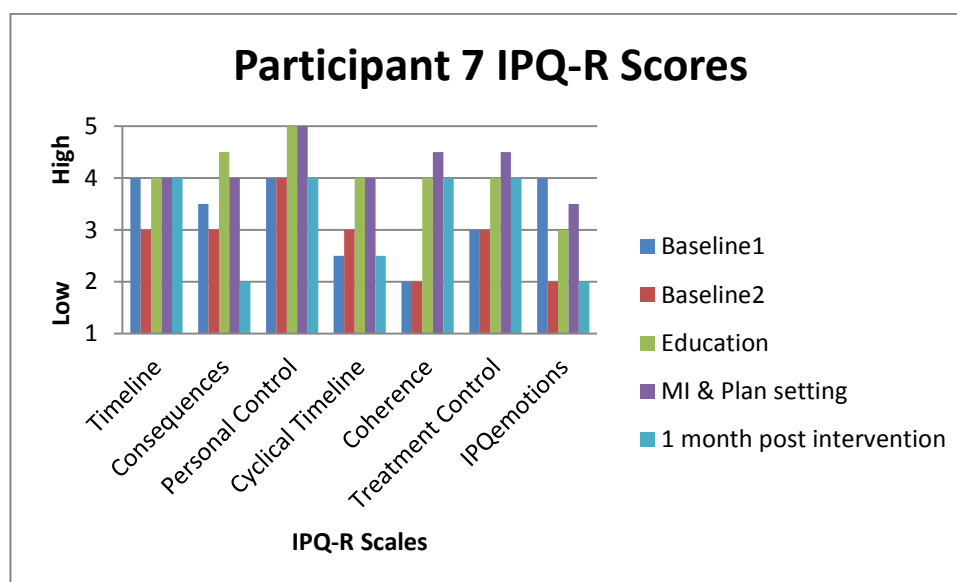


Figure 24. Participant 7: IPQ-R scale scores pre-, during and post-intervention

For medication beliefs, participant 7's necessity score increased after her MI session, but decreased by one month post-intervention (see Figure 25). Her concerns about medication scores fluctuated during the study, though after the hospital session her concerns score remained low.

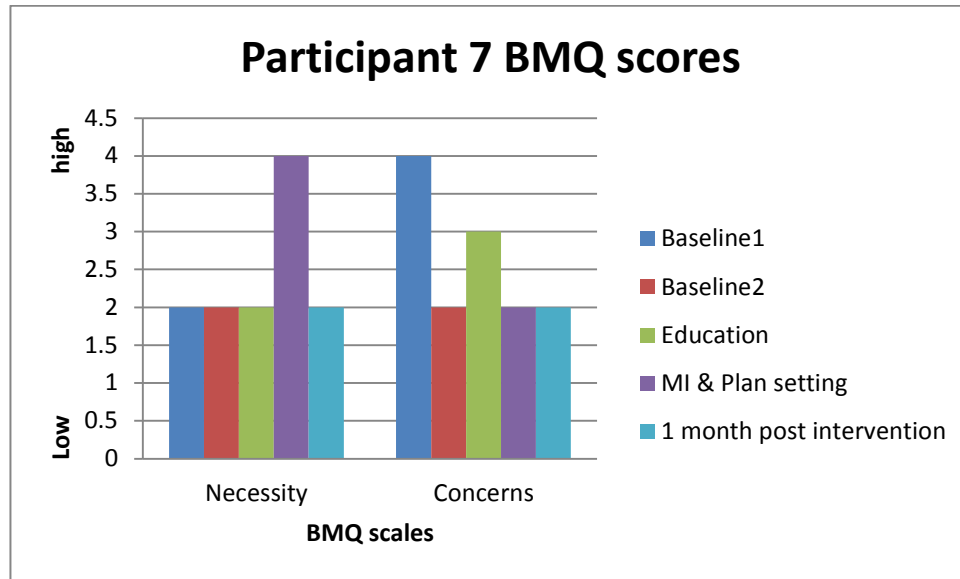


Figure 25. Participant 7: BMQ scale scores pre-, during and post-intervention

Medication efficacy gradually increased after baseline 2 for participant 7 (see Figure 26). Susceptibility to fractures increased after the hospital session and increased slightly more post-intervention. Self-efficacy increased slightly after the MI and plan-setting session.

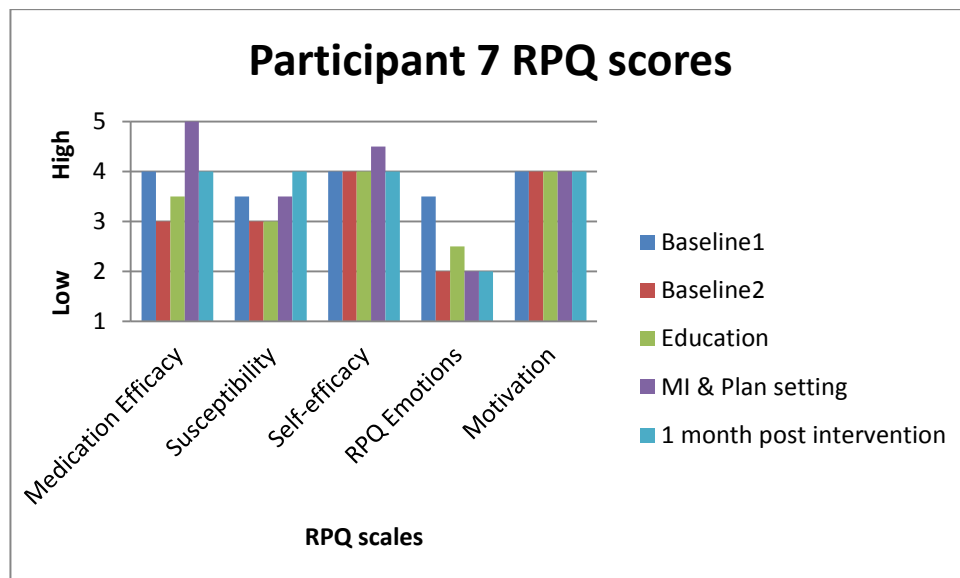


Figure 26. Participant 7: RPQ scale scores pre-, during and post-intervention

In contrast to many of the other participants, participant 7's drawings of osteoporosis were much larger post-intervention.

Participant 8

Participant 8 was a 69 year old woman who was diagnosed with osteoporosis for 15 years at the time of the study and had suffered no fractures. She was in part-time employment (three days per week). She said it was likely that her mother also had osteoporosis, though it was not diagnosed. She was initially prescribed two different bisphosphonates for osteoporosis, but had to stop taking them both due to side effects. As well as osteoporosis, she had an overactive thyroid. She was prescribed three medications: thyroxine, vitamin D and SR. She reported that although she took her thyroxine and vitamin D with no problems, she had failed to initiate her SR prescription. At baseline 1 she said I 'have some psychological block following the previous experiences with osteoporosis medications.' There were three months between her two baseline assessments.

During the intervention she initiated her SR and her adherence gradually increased. She initially planned to take her medication on her work days, so was able to take it for three days a week. In her follow-up 'phone call we revised her plan so that she could find a way to take her medication on her days off work. She identified that on Sundays she could take the medication in the morning before church, giving her enough time to fast, because she always had her breakfast when she got home from church. On her other days off work she planned to take the medication in the afternoon between a four hour fast after lunch and before dinner.

The majority of participant 8's scores remained stable during the study period. She had high perceptions of: timeline, personal control and perceived coherence (see Figure 27). She had low perceptions of cyclical timeline, consequences and a low emotional response to the condition. Her perception of treatment control increased after she received the information booklet and again after the MI and plan-setting session. Between assessments four and five, participant 8 had a high blood pressure reading, which meant that her prescribed for SR had to be temporarily suspended, due to the recently evident links between taking SR and cardiovascular events (MHRA, 2013).

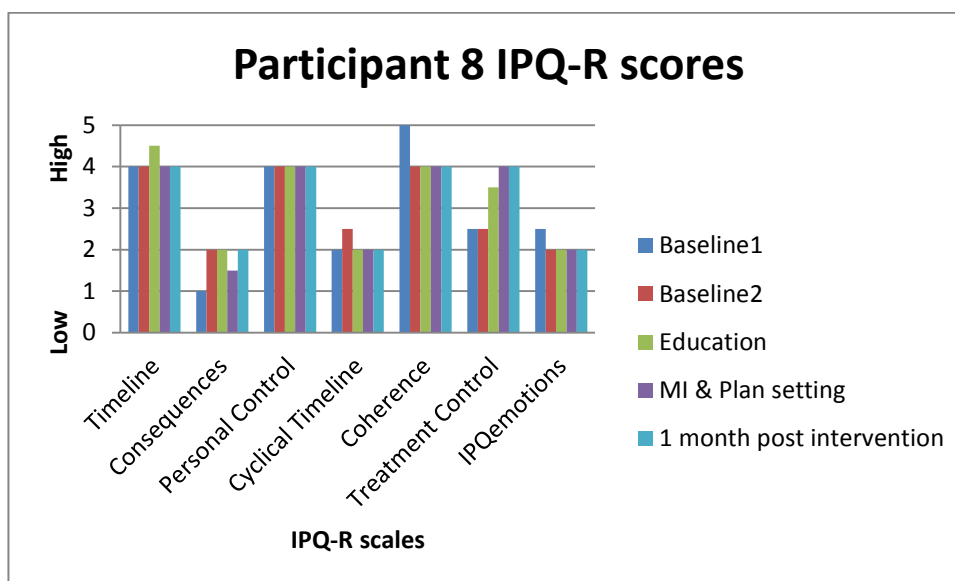


Figure 27. Participant 8: IPQ-R scale scores pre-, during and post-intervention

Her concerns about medication fluctuated slightly and she remained unsure of the necessity for the medication throughout the intervention period and at follow-up (see Figure 28).

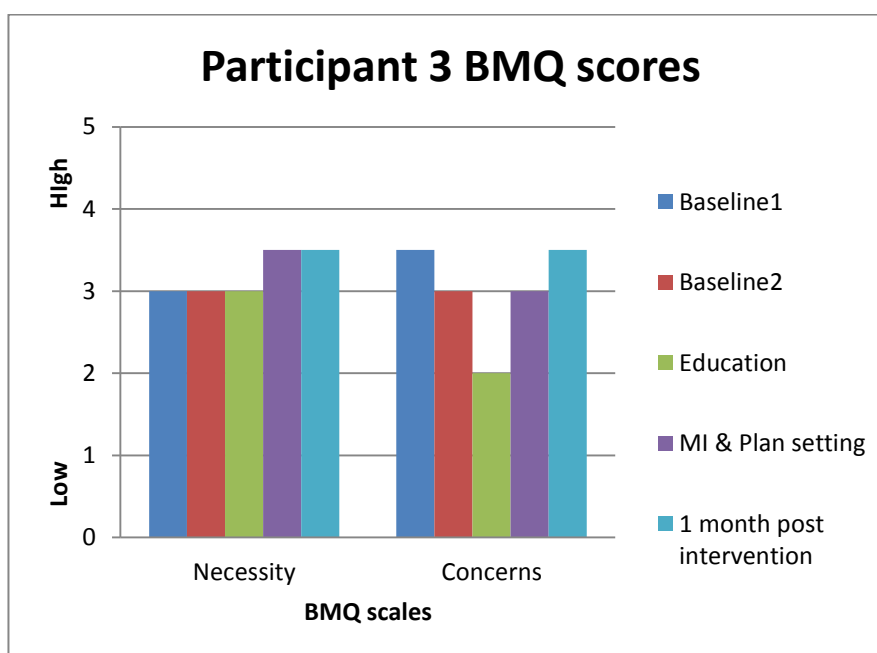


Figure 28. Participant 8: BMQ scale scores pre-, during and post-intervention

Although participant 8's motivation had dropped at baseline two, it increased after she received her information booklet (see Figure 29). Her self-efficacy was extremely low

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after the information booklet, but increased slightly after the MI and plan-setting session. As for IPQ emotions, RPQ emotions remained low during and post-intervention.

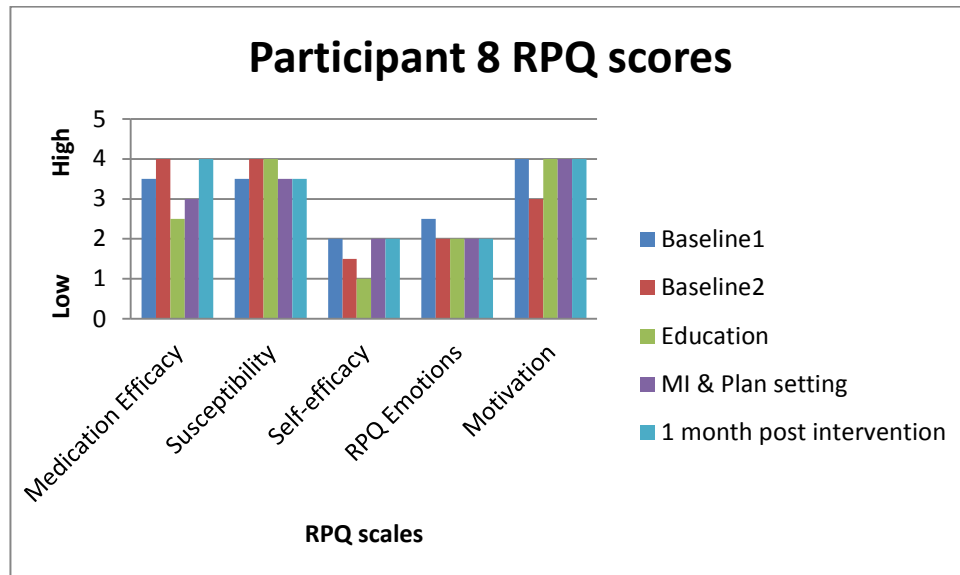


Figure 29. Participant 8. RPQ scores pre-, during and post-intervention

Group 2: Participants who were taking their prescribed strontium ranelate at baseline

Participant 1

Participant 1 was a 59 year old woman who was diagnosed with osteoporosis five years prior to the study and had suffered no fractures. She was in full-time employment. She had no family history of osteoporosis. She said she was shocked with her diagnosis of osteoporosis due to her age (54) at the time of diagnosis. She said her age made it difficult to accept the diagnosis of osteoporosis, because she believed it to be a condition suffered by older people. Between the two baseline measures she went through many changes. At baseline 1 she was a smoker, diagnosed with depression and she was prescribed anti-depressants. However, by baseline 2 she had ceased smoking and was no longer prescribed with anti-depressants. At baseline 1 she was prescribed with alendronic acid for osteoporosis, but she had difficulty with taking it and eventually had to terminate it due to the side effects she experienced. By her baseline 2 assessment, her osteoporosis medication prescription had been changed to

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SR with vitamin D supplementation. She reported that the four hour daily fasting required was her major barrier to taking SR. There were 18 months between baseline 1 and baseline 2.

During the hospital session she identified her main motivation to take the medication was that she wanted to improve and be 'as good as possible'. She welcomed the opportunity to make a plan for taking her medication. Her plan involved taking SR at night before she went to sleep and as a back-up to take it in the middle of the night when she woke up. She also set a reminder on her mobile phone during the hospital appointment. In her follow-up 'phone call we did not need to make any amendments to her plan because she said her original plan worked very well. Throughout the intervention her medication-taking increased, though it appeared to have decreased at the end of the intervention on one of the adherence measures (see Figure 15). The participant attributed her missed doses of SR to being away on a holiday for the last month of the intervention.

The majority of participant 1's illness perceptions remained stable throughout the course of the intervention, with an increase in perceived coherence after she received her tailored information booklet (Figure 30).

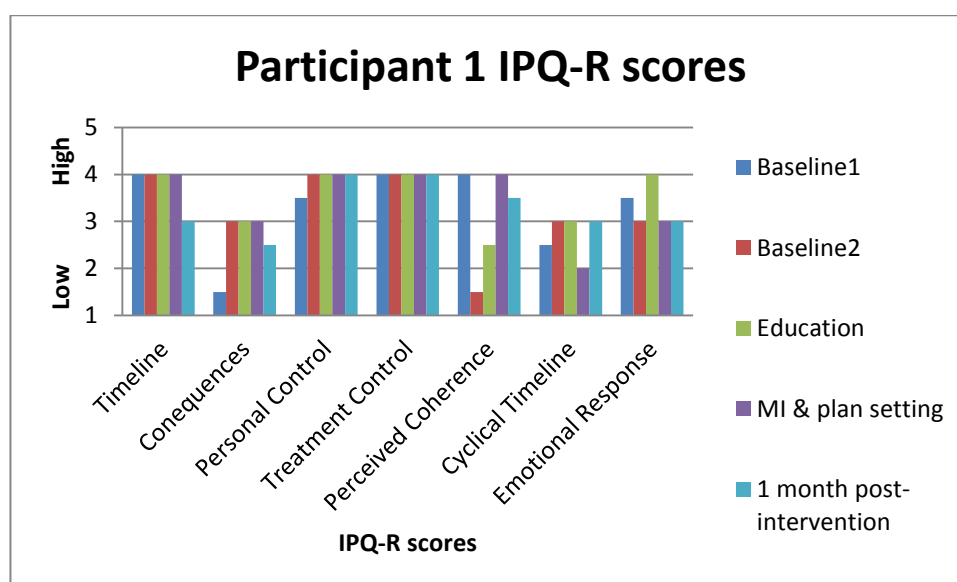


Figure 30. Participant 1: IPQ-R scale scores pre-, during and post-intervention

Participant 1's concerns about medication score decreased over the course of the intervention (see Figure 31). Her necessity beliefs increased after the MI and plan-setting session.

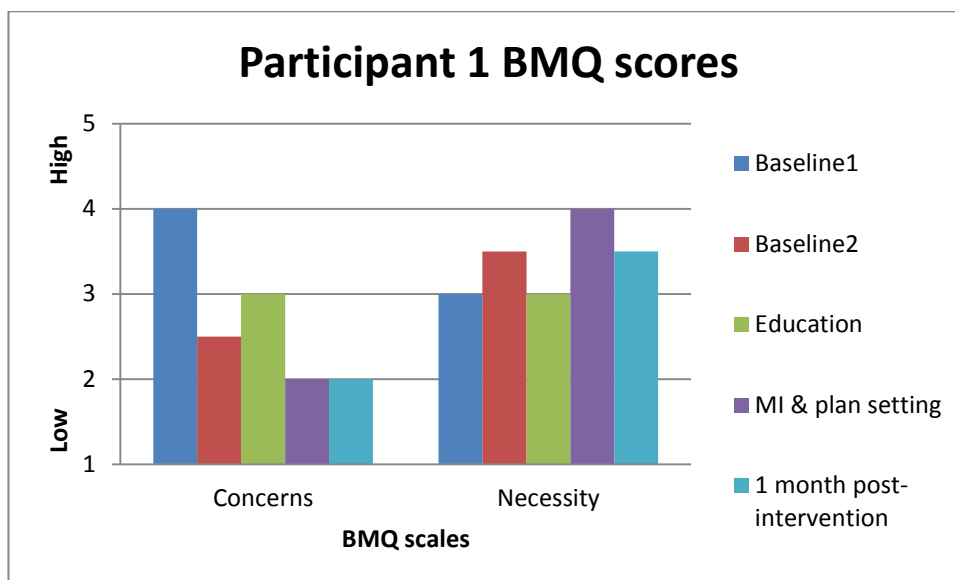


Figure 31. Participant 1: BMQ scale scores pre-, during and post-intervention

Participant 1's RPQ scores fluctuated throughout the course of the intervention, with motivation to take SR remaining high throughout the entire study (see Figure 32).

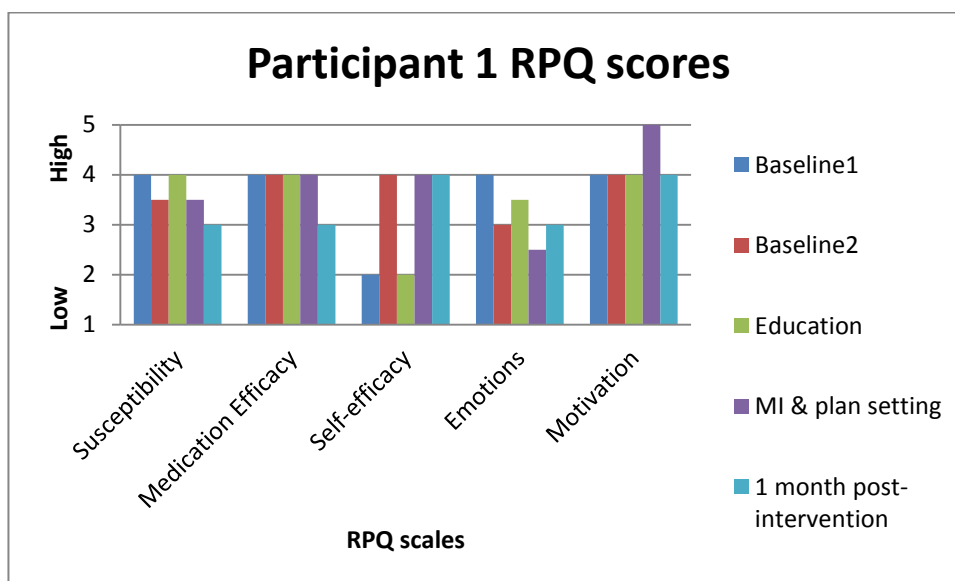


Figure 32. Participant 1: RPQ scale scores pre-, during and post-intervention

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Figure 32 shows that self-efficacy was maintained one month post-intervention, but her belief in the medication efficacy decreased one month post-intervention, to indicate that she was unsure about the medication efficacy.

Participant 2

Participant 2 was a 68 year old woman who was diagnosed with osteoporosis 16 years prior to the study and had suffered no fractures. She was in full-time employment. There was no history of osteoporosis in her family. As well as osteoporosis, she suffered from high blood pressure, dry skin and dry eyes. She was prescribed with four medications for these conditions, this increased by one during the winter, during which time she was additionally prescribed vitamin D for osteoporosis, due to a lack of sunlight during the winter. Although her MARS score at baseline was 21/25, she reported no barriers to taking SR. During the course of the intervention her adherence scores were high and stable. She did not exhibit many problems with medication adherence.

During her hospital session she said that to remind herself to take her medication before she goes to sleep, her medication is kept next to her bed. She reported that her motivation for taking the medication was that she wants to improve her bone health. The patient's total barriers to adherence increased from zero to two during the intervention. While initially at baseline 1 she reported no barriers, she reported that when she felt unwell (e.g. with a cold) she would not take her SR.

Although in terms of adherence it seemed that the patient perhaps did have any serious problems of missing doses, her highest MARS score was recorded at one month post-intervention. There were some positive changes in the direction of her beliefs, towards being more concordant with those of healthcare professionals. During and post-intervention the following scores increased: timeline scores, personal control, coherence, treatment control scores (see Figure 33), demonstrating a better understanding of the condition.

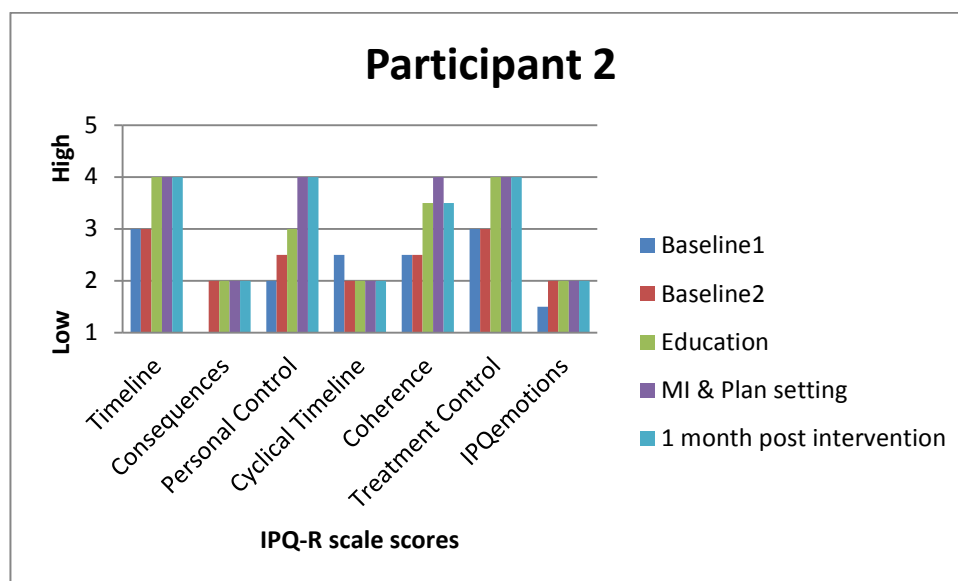


Figure 33. Participant 2: IPQ-R scale scores pre-, during and post-intervention

While there were also changes in her BMQ scale scores, there were no changes in her RPQ scores. Participant 2's beliefs in the necessity of the medication increased particularly after the MI session (see Figure 34). Concerns about medication fluctuated pre-, during and post-intervention. Participant 7 asked some questions about the safety of SR. During her hospital session she reported that having the opportunity to ask about the long term safety of the medication had reduced her concerns about taking it.

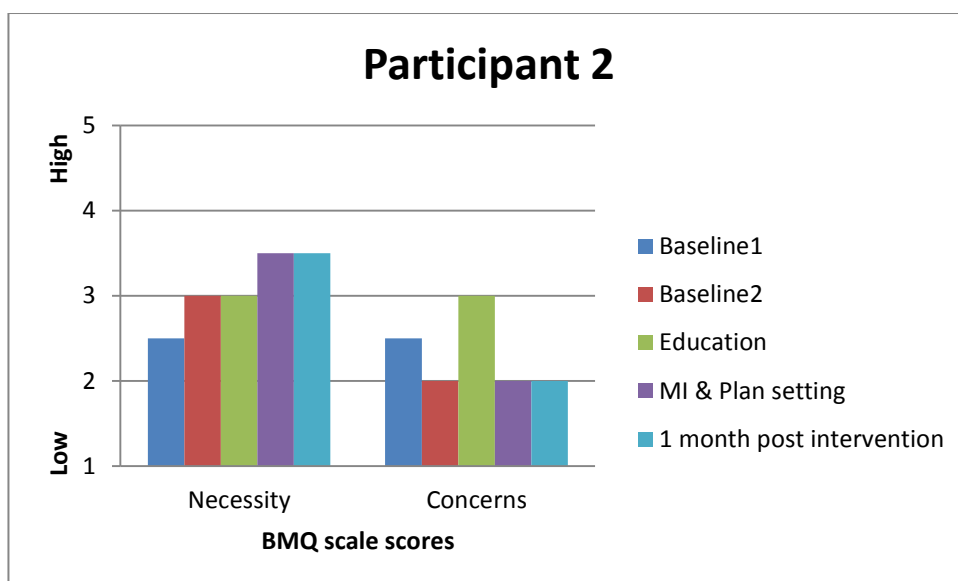


Figure 34. Participant 2: BMQ scales, pre-, during and post-intervention

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At baseline 1 this participant did not produce any drawings of osteoporosis. She reported that she did not know what to draw. Even after being given some encouragement she said she did not know what to draw. However, in her final assessment (one month post-intervention), she was able to create some drawings of osteoporosis.

Participant 4

This participant was a 61 year old woman who had suffered with osteoporosis for three years and had sustained seven fractures in her lifetime. Her mother was also diagnosed with osteoporosis. As well as osteoporosis she suffered with chronic back pain, for which she was prescribed daily exercises. At baseline she reported two barriers to adherence, with the main one as 'the timing, leaving two hours after eating is tricky when occasionally dinner is late.' There were two years between the two baseline assessments.

Her MARS score at baseline one was 22/25, therefore she was on the borderline cut-off to indicate non-adherence. Over the course of the intervention it became apparent that she occasionally missed doses, but on the whole she took her medication as prescribed. Her MARS score had improved by baseline two. During her MI session she reported that her motivation for taking the medication was that she trusted her doctor's expertise. She had already developed a routine for taking her medication, so during the plan-setting her plan was reaffirmed. She was congratulated for taking her medication as prescribed and her question was addressed by a medical specialist about whether she could take pain killers during the four hour fast.

Some of participant 4's illness perceptions increased in the desired direction; timeline and treatment control (see Figure 35). Her perceived coherence increased after receiving the information booklet and remained high at each following assessment. Her emotional response and perceived negative consequences scores fluctuated. Her rating of personal control increased at the assessment after the information booklet, but decreased by the following assessment.

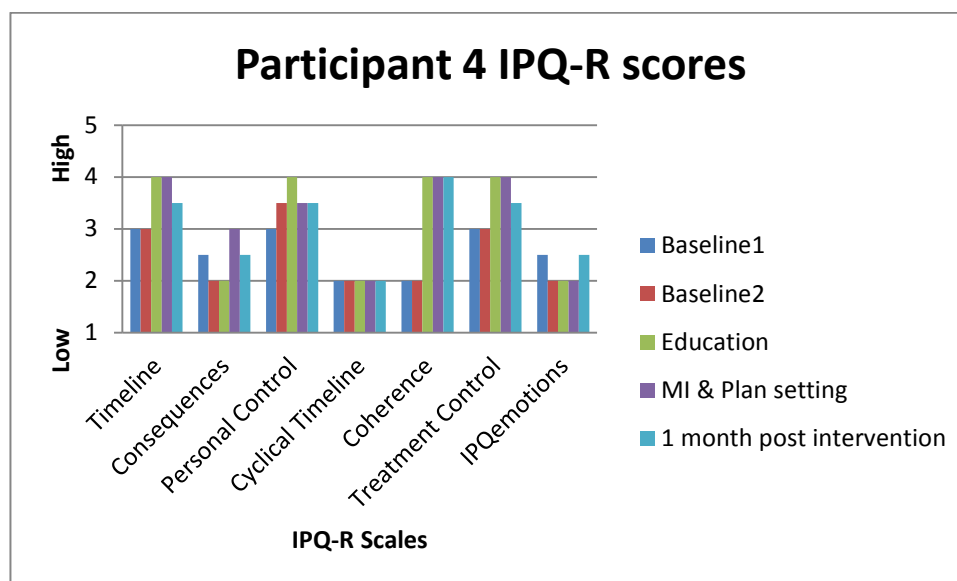


Figure 35. Participant 4: IPQ-R scales, pre-, during and post-intervention

Participant 4 scored low on both of the medication beliefs measured; necessity and concerns (see Figure 36). Her necessity scores fluctuated slightly, whereas the concerns score remained stable. She disagreed that SR was a cause for concern. Even though she reported having faith in her doctor's prescription of SR, she was still unsure of the need for it.

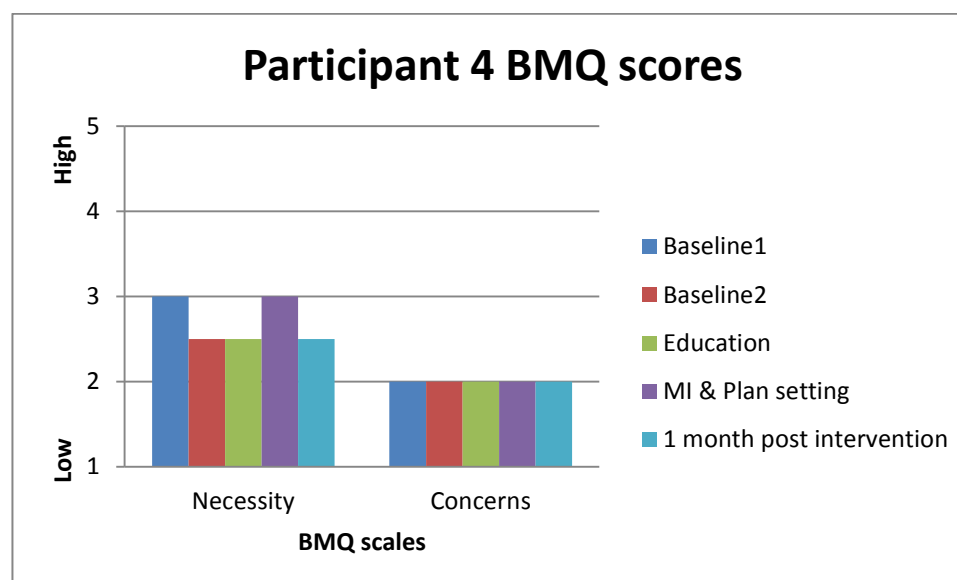


Figure 36. Participant 4: BMQ scale scores, pre-, during and post-intervention

Participant 5's motivation and susceptibility to fracture remained high throughout the study period (see Figure 37). This high susceptibility score is likely to be related to her having experienced seven fractures prior to the study. Her medication efficacy follow a similar pattern to the IPQ-R treatment control score, it increased immediately after receiving the information booklet, but then decreased post-intervention. This participant's self-efficacy score fluctuated but remained high post-intervention.

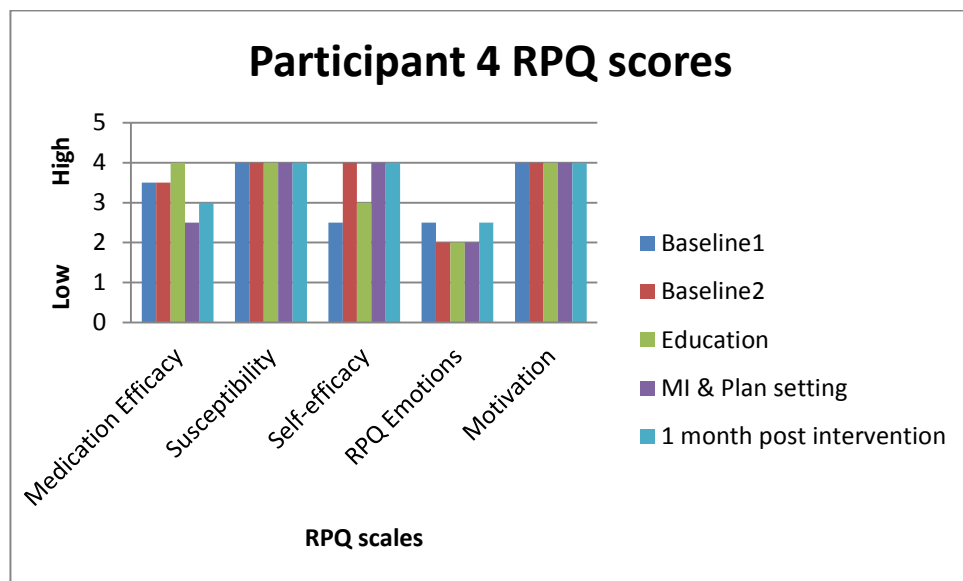


Figure 37. Participant 4: RPQ scale scores, pre-, during and post-intervention

Participant 6

Participant 6 was a 58 year old woman who was diagnosed with osteopaenia approximately five years prior to the study and had suffered no fractures. The diagnosis was later upgraded to osteoporosis. She was in the process of changing jobs at the time of the study. Her mother was also previously diagnosed with osteoporosis. Apart from osteoporosis she had been previously diagnosed with pancreatitis. In the time between her two baseline measures (six months), she did not experience any changes in clinical or social context. Apart from her SR she was also prescribed vitamin D for osteoporosis. Her MARS score at the first baseline was 18/25, with three missed doses of SR for the month she was assessed. On the baseline total barriers questionnaire, she reported 'would like to see a better explanation of my condition when face-to-face with my consultant.'

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During participant 6's MI session she reported that her experience of being hospitalised with pancreatitis motivated her to take her medication as prescribed. She asked a large number of questions in the opportunity she was given during the educational telephone follow-up. These questions were referred to her osteoporosis consultant and addressed during her MI session. The osteoporosis consultant advised that the patient should make an additional appointment to see her consultant if she still had unanswered questions. During her MI session, her current plan for taking the medication, which she had initiated before her participation in the intervention was re-affirmed. Her plan involved taking the medication at night before she went to sleep and as a back-up to take it in the middle of the night when she woke up. In her follow-up 'phone call we did not need to make any amendments to her medication plan because her original plan worked well. Throughout the intervention her medication-taking increased at each time point and also increased post-intervention (see Figure 15 and Figure 16).

Perceived coherence increased for participant 6 after she received her information booklet (see Figure 38). This change was maintained one month post-intervention. Her perception of treatment control increased during the course of the intervention. Her emotional response was lower during the intervention than it was at the pre- and post-intervention assessments.

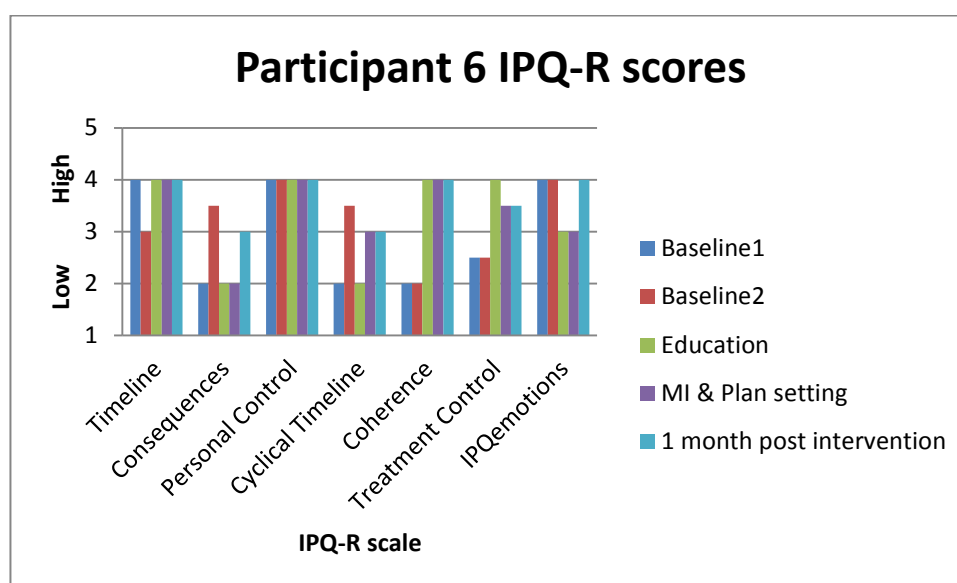


Figure 38. Participant 6: IPQ-R scale scores pre-, during and post-intervention

Both sets of medication beliefs fluctuated during the intervention for participant 6 (see Figure 39). After the MI session she was unsure about whether she was concerned about her medication, whereas before this she disagreed that she had concerns about taking SR.

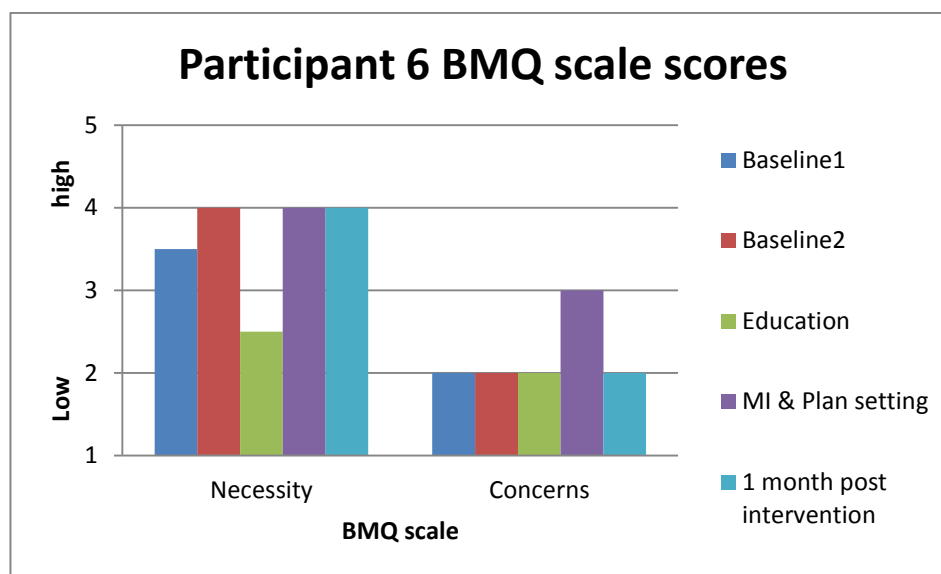


Figure 39. Participant 6: BMQ scale scores pre-, during and post-intervention

Participant 6 showed a reduction in emotional response to osteoporosis in the risk perceptions measure (see Figure 40), in contrast to the IPQ emotions score. Self-efficacy and motivation were high from baseline until the final assessment.

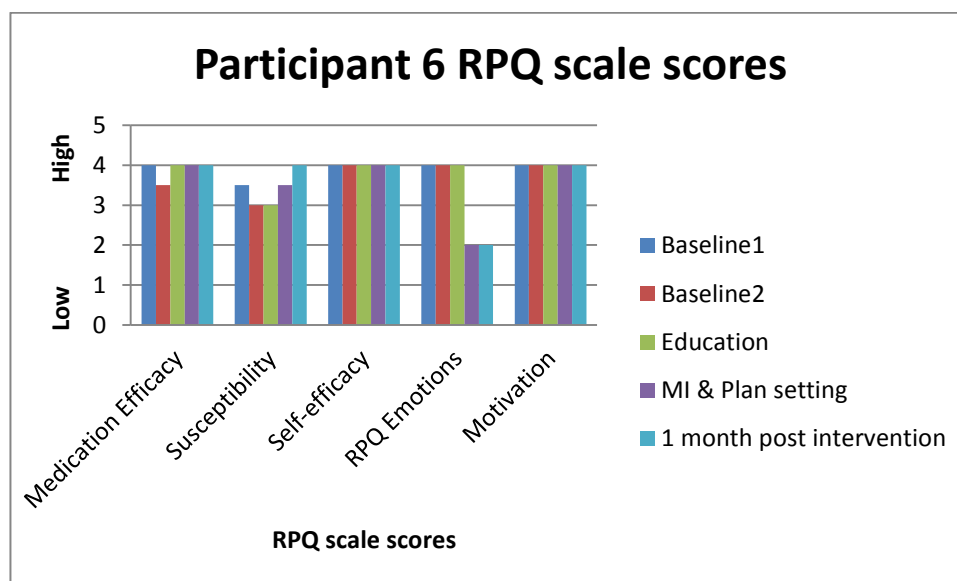


Figure 40. Participant 6: RPQ scale scores pre-, during and post-intervention

9.6.3 Were there changes in patient's depictions of osteoporosis after the intervention?

Six of the eight participants created a pair of drawings of bones and people with and without osteoporosis both pre- and post-intervention. One participant completed the drawings at the post-intervention assessment only and one participant refused to create any drawings of osteoporosis.

Table 36. Example of participant drawings pre- and post-intervention

	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

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Length

Measurements were taken through the longest line of both the pre- and post-intervention drawings (Table 37). When the measurements of drawings pre- and post-intervention were compared, four out of six participants produced smaller drawings of bones in the post-intervention assessment.

Table 37. Drawings of bones with and without osteoporosis; measurements through their longest line, pre- and post-intervention

Participant Number	Bone with osteoporosis Pre-intervention (cm)	Bone with osteoporosis Post-intervention (cm)	Bone without osteoporosis pre-intervention (cm)	Bone without osteoporosis post-intervention (cm)
1	12.5	6.0	12.6	7.1
2	-	4.9	-	5.0
3	-	-	-	-
4	2.4	1.3	2.3	1.7
5	2.3	1.6	2.0	1.6
6	3.6	3.7	2.9	3.1
7	7.3	12.3	5.1	12.2
8	8.7	6.9	9.5	7.4

Shape

The majority of participants created drawings of stereotypical type bones (see the example shown in Table 36). Two participants drew cross-sections of bones pre- and post-intervention, with one additional participant drawing a cross-section post-intervention.

Bone deformity

Two participants did not draw holes/pores on their drawings of bones without osteoporosis in the pre-intervention assessment. Post-intervention, one of these

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participants drew holes/pores on the normal bone. Participants used holes or shading to signify bone damage. Although it appears that some patients used shading to signify bone damage, others used shading to indicate that the bones were stronger.

Drawings of people with and without osteoporosis

Length

Table 38. Drawings of people with and without osteoporosis; measurements through their longest line, pre-and post-intervention

Participant Number	Person with osteoporosis Pre-intervention (cm)	Person with osteoporosis Post-intervention (cm)	Person without osteoporosis pre-intervention (cm)	Person without osteoporosis post-intervention (cm)
1	8.4	3.1	11.1	5.0
2	-	5.7	-	5.6
3	-	-	-	-
4	5.1	4.2/5.0*	4.9	2.8/3.5*
5	1.1	1.1	1.1	1.4
6	7.4	9.3	9.1	9.2
7	3.0	17.8	4.4	17.8
8	5.6	5.0/3.5*	5.2	3.6

*Two figures are provided when the participant produced two drawings.

Fifty per cent of the participants created drawings of people with and without osteoporosis smaller in their post-intervention assessment than in their pre-intervention assessment. One participant did drawings of people with osteoporosis pre- and post-intervention which were almost identical and were the same size.

Two participants drew faces on their post-intervention drawings of people without osteoporosis, whereas in the pre-intervention assessment they did not. One of these participants drew no faces on her pair of pre-intervention drawings and faded faces on

her post-intervention drawings of people with and without osteoporosis. One participant drew her post-intervention pictures as male where as her pre-intervention pictures were female.

9.6.4 Were there common trends between participants?

There were common trends for the following beliefs: treatment control and necessity for medication. The data showed that perceived coherence increased for all participants during the intervention period. This increase was maintained for all but one participant at the post-intervention assessment. As can be seen in the graphs above for each participant, the scores for the majority of psychological factors fluctuated over the intervention period. It was common for emotional responses, medication efficacy and concerns about medication scores to fluctuate. There was one exception to this; participant 8's scores stayed fairly constant across all the scales measured, apart from her medication adherence scores which increased.

Perceived coherence increased for all participants, with the exception of participant 3, who, during the intervention period, received some information from her osteoporosis consultant that the medication was potentially unsafe for her use. Her perceived coherence increased after the information booklet and decreased by the final assessment. One participant reported more barriers post-intervention than she did at her pre-intervention assessment (participant 2).

It is noteworthy that three participants' self-efficacy decreased in the assessment after they received their information booklet (participants 1, 4 and 8), but increased for 3 participants after the MI and plan-setting session. Susceptibility to fracture decreased for three participants between baseline and the end of the intervention (participants 1, 5 and 6).

Of the seven participants who showed an increase in adherence throughout the course of the intervention, six created a drawing of their condition before and after the intervention. Five of these participants showed either an increase or a decrease in size of their drawings of bones post-intervention. The participant whose adherence did not

change during the intervention (participant 5) produced drawings of a very similar size in her pre- and post-intervention assessments.

9.7 Discussion

Key findings

This theory-based adherence intervention aimed to reduce intentional and unintentional non-adherence to osteoporosis medication. Self-reported adherence increased for seven of the eight study participants during the course of the intervention. Four of the participants were not taking their prescribed medication at the outset of the study and three of this group initiated their medication during the intervention period. The other four patients were taking their SR prior to the intervention but with some difficulty, all of them increased their adherence throughout the intervention.

These results are in contrast to those of a previous intervention. Guiler (2006) carried out an intervention using education, motivational interviewing and telephone follow-up. The study participants showed no increase in adherence to medication. There are three key differences which might be responsible for the differences in the results observed. In the present study theory was used to select the educational materials, the educational materials were tailored to individuals needs and implementation intentions (plan-setting) was added to the components mentioned above. Given the strong links between self-efficacy and adherence observed in study 3, it is possible that the implementation-intentions element was an effective ingredient of the ATOM intervention.

An important question for discussion is whether the observed changes in adherence can be attributed to changes in beliefs or other psychological constructs? Studies of a larger sample size are required to provide an answer to this. There is some support for changes in psychological constructs resulting in changes in adherence, because there were three constructs (perceived coherence, treatment control and a belief in the necessity of the medication) for which increases were observed in the majority of the study participants. Further, the fluctuation observed in participants' scores for many of

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the psychological constructs measured provides some support for the extended self-regulation model (SRM), where participants are continuously evaluating their condition, assimilating new information and updating their cognitive and emotional representations of their condition.

It is possible that the increase in perceived coherence is a factor which led to increased adherence. This finding supports Leventhal's SRM, that patients are more likely to select a problem-focused coping mechanism if they have a coherent understanding/model of their condition (Leventhal et al, 1984). Another mechanism which may have increased adherence was the increase in perceived need for medication, which was previously documented to be related to osteoporosis medication persistence (Schousboe et al, 2010). Perceived necessity increased for six of the eight patients, though in the final assessment for one of the patients it dropped back to the same low level it was at baseline.

Treatment control ratings increased for all the study participants. This is another possible mechanism through which the intervention might be effective. There was not such a clear increase in the belief in medication to reduce the chance of fracture (RPQ medication self-efficacy scale), with many participants' scores fluctuating throughout the intervention. This indicates that perhaps while it is possible for patients to understand that the medication can control osteoporosis, they find it very difficult to comprehend that medication has the specific role to reduce fracture risk.

This N-of-1 trial was beneficial in determining who the intervention was appropriate and beneficial for. Only one of the study participants did not benefit from the intervention in terms of adherence. Another two participants did not have large increases in adherence, because their MARS scores were on the border line for non-adherence. Both participants scored low on DOTMQ at baseline 1, reporting very few barriers to adherence. In future studies, both the MARS score and the total barriers scores could be used to identify patients who require an intervention to improve adherence. However, while they did not benefit in terms of large increases in adherence, there were other changes which are likely to help them to manage their

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condition better. For example, perceived coherence and treatment control increased for each of these participants.

In terms of negative effects, there were a few potentially problematic effects noted in the results section. Self-efficacy decreased for some patients after they received their information booklet, but increased after the MI and plan-setting session. Perhaps this explains why education is not always effective in increasing adherence as would be hypothesised. The information booklet may have been difficult for the patients to assimilate if they had not been followed-up and assisted to make a medication plan if needed, rather than just leaving them with difficult information. However, a larger powered study is needed to investigate this further. Perceived susceptibility to fracture also reduced for some participants after the intervention. While this could be a negative effect, it could also be positive. Perhaps some patients felt less susceptible to a fracture post-intervention, given that they are taking steps to prevent fractures through increased adherence.

Asking patients to do simple sketches of their condition pre-and post-intervention has provided some insight into how they perceive their condition. It is interesting that four out of six participants' drawings were smaller in their post-intervention assessment than in their pre-intervention assessment. This finding is in agreement with the findings of previous researchers, that patients' drawings become smaller after an intervention to manage a health problem (Broadbent et al, 2006a). Perhaps this indicates that the intervention helped patients to feel that they could cope effectively with their condition.

A major question for discussion is, were the changes in osteoporosis patients' beliefs and adherence the result of the Hawthorne effect? There are other factors which may have led to increases in patients' adherence such as: the attention they received, the social interaction, an educational class, or a medical consultation attended by a participant? To monitor this contextual data was collected. As shown in the case study narratives, there were no reports of any significant events which might alter beliefs or medication-taking, e.g. major changes in medical condition or a fracture. With this

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small sample size, it is not possible to attribute the changes observed in patients to the intervention, as it is not possible to determine whether the changes were due to chance, or a factor other than the intervention. However, the evaluation data suggest that participants believe their adherence improved as a result of the intervention and no other factors (see following chapter).

Limitations

The time available for follow-up for the assessment of adherence and psychological factors was limited, with the final follow-up at 1 month post-intervention. This poses an important limitation, where is it unknown whether and for how long the increases in adherence were sustained. This raises the question of how long an intervention of this nature would be anticipated to increase adherence for. Without a control group, the results are only valid for the patients in the study. Considering this, there could have been extraneous variables other than the intervention that had an effect on adherence or psychological factors.

This intervention focused upon self-management of osteoporosis, particularly using medication. While information about diet and falls prevention was also included in this intervention, due to time limitations it was not possible to include the management of other medical conditions. Participants in study 2 and the present study discussed that managing multiple comorbidities with multiple medications was a problem for them. Therefore future, larger scale studies could benefit from taking this into account.

The varying time lag between baseline one and baseline two assessment is problematic when comparing data between baseline one and baseline two. Some patients had their first baseline assessment two years before their second assessment. This problem resulted from the difficulties of recruiting patients for study 3, which meant that study 5 started much later than originally planned.

9.8 Conclusions

Adherence increased for the majority of osteoporosis patients who took part in the ATOM intervention. For patients who did not show large increases in medication

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adherence, there were other benefits to taking part, particularly an increase in their understanding of the condition and the need for medication. The evaluation of the outcome data suggests that changes in behaviour may have been brought about by the changes in perceptions observed throughout the study for many participants:

- Increases in perceived coherence or understanding of the condition
- Increased belief in the ability of treatment to control osteoporosis
- Increased belief in the necessity of medication for the treatment of osteoporosis

10 Study 6: Process evaluation of a complex behaviour change intervention to increase adherence to osteoporosis medication

Chapter overview

The major benefit of delivering an intervention using a case-series approach is the opportunity to carry out detailed evaluation of the intervention process with all of the study participants. This provides an opportunity to gather detailed information about patients' subjective experiences of the intervention. Following the MRC's framework for the design and evaluation of complex interventions, the evaluation data can be applied to the intervention in order to improve and refine it for future use in a randomised controlled trial. The aim was to understand patients' perceptions of the intervention and to determine the mechanism of change. This chapter presents the results of the process evaluation of the ATOM Study and provides a theory for the mechanism of change in adherence observed in the study participants.

10.1 Introduction

While there are a multitude of published interventions to promote adherence, few have been evaluated in sufficient detail (Gleeson et al, 2009). In order to design more effective interventions, the MRC recommends the inclusion of a detailed evaluation, built into the intervention design (MRC, 2008) to identify the active/effective ingredients. There are two main issues which can be addressed in a process evaluation; why was the intervention (un) successful and how can it be optimised? (MRC, 2008). It is also important to gain an understanding of individual variation in response to different intervention components.

There are few guidelines for process evaluations of interventions delivered to patients (Grant et al, 2003). There is a growing literature on the evaluation of complex interventions, with many previously published interventions focussing on the behaviour change of healthcare professionals, to promote evidence-based healthcare practice. For example Normalisation Process Theory (NPT) (May & Finch, 2009) can be

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used to evaluate the effectiveness of interventions delivered by Healthcare Professionals (HCPs).

NPT focuses on 4 components of an intervention:

'NPT is concerned with identifying and understanding the ways that people make sense of the work of implementing and integrating a complex intervention (coherence); how they engage with it (cognitive participation); enact it (collective action); and appraise its effects (reflexive monitoring).'' (May & Finch, 2010).

Leaving aside the issue of implementation, NPT can be used to guide evaluation which focuses on how patients experienced the intervention, including whether it made sense to them. In addition, Grant et al (2013) suggested that the maintenance of the target behaviour should be evaluated after the intervention is completed. For the present pilot trial, it was essential to determine what worked well and what did not, so that it can be developed and made useful for larger groups of patients. This process evaluation used an adaptation of NPT (May & Finch, 2010) and process evaluations for cluster randomised controlled trials (Grant et al, 2013) in order to evaluate the process, effectiveness and acceptability of the ATOM intervention.

Research questions

- What were the mechanisms of the changes observed in adherence and/or psychological factors?
- What was each participant's subjective experience of taking part in the adherence intervention research?
- Were participants' satisfied with the different components of the intervention?

10.2 Method

10.2.1 Research design

The participants were the eight osteoporosis patients who received the ATOM intervention presented in study 5. Mixed methods were used, utilizing both Likert scales and in-depth qualitative interviewing. This chapter is the result of the process evaluation, using data collected at two points during the intervention.

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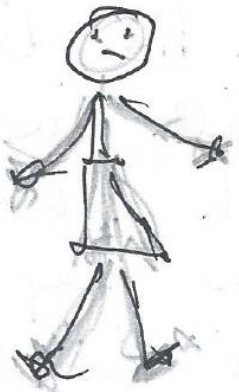



The reasons patients decided to participate in the intervention were explored, using the NPT (May & Finch, 2009). In addition, the effectiveness and maintenance of the intervention were explored using the framework for the design and reporting of complex intervention evaluations (Grant et al, 2013). The duration of the interviews was between 35 minutes and 1 hour 15 minutes.

10.2.2 Measure

In the first phase of the process evaluation patients were asked ‘what did you think of the information booklet you received in the post?’ In the second phase, interviews were carried out to explore patients’ perceptions of the purpose of the intervention. Based upon two components of NPT, the reasons for participation were explored, as well as their understanding of the objective of the intervention (May & Finch, 2009). NPT was originally designed to evaluate the delivery of interventions by healthcare professionals. Therefore some of the elements of NPT were not relevant for a process evaluation of an intervention from the perspective of research participants. The elements not relevant to study participants were collective action and reflexive monitoring. In addition, effectiveness and maintenance of the intervention were explored using the framework for the design and reporting of complex intervention evaluations (Grant et al, 2013). The interview schedule can be found in

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Table 62. Participant 8. People drawings

	Pre-intervention	Post-intervention
With osteoporosis		<p>Could look the same as without osteoporosis</p>  <p>Or</p> 
Without osteoporosis		

APPENDIX 26. The interview questions were adapted slightly for each participant, so that they were asked about the individual components of the intervention they received. For example, patients who received the decisional balance element of the intervention were questioned about it, but for those that did not receive decisional balance, the question was not appropriate and so was excluded from their interview.

10.2.3 Procedure

The first phase of the evaluation assessed the information booklet with an open ended question to enable participants to provide feedback. This took place one week after participants received the information booklet. Following this, the process evaluation of the entire intervention was carried out by an independent assessor at the end of the study. An independent assessor was necessary in order to reduce bias in patients' responses, which may have been introduced if the evaluation was carried out by the author, given that the author designed the intervention. A semi-structured interview using both open-ended questions and Likert scales was used to collect data. Each phase of the intervention was evaluated close to the time it occurred to minimise bias and memory confounders.

10.3 Analysis

A research assistant conducted framework analysis for this process evaluation. The rationale for this was to enable the intervention to be analysed by an individual who was not involved in the intervention design, to reduce the risk of bias. Two transcripts were analysed for themes by both the author and the independent assessor, who then met to discuss the coding framework. Both researchers recorded the themes they had identified on post-it notes, so that themes could be easily moved to another category if required. Any disagreements were discussed until consensus was reached. The independent assessor analysed the remaining transcripts, which were then interpreted by the author.

10.4 Results

The results section presents firstly the evaluation of the information booklet, before progressing to the evaluation of the entire ATOM intervention. All eight study

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participants provided useful evaluations of the intervention. The themes that emerged from patients interviews are presented below. Three overarching or 'global themes' were used to categorise the data: pre-intervention thoughts and behaviours, post-intervention changes and the intervention. The following sections present a summary of the data which can be used to answer each research question. Before the results of the thematic analysis, the evaluation of the information booklet is presented.

10.4.1 Evaluation of the information booklet

The vast majority of patients reported that they liked the information booklet and that they were able to learn new facts about osteoporosis. Patients' comments about the booklet were divided into positive and negative responses and are shown in Table 39. Two participants however, felt neutral about the booklet, they neither rated it positively or negatively. These are participants 2 and 3 who have missing data below. The comments were not transcribed verbatim and are summaries of each patient's comments.

Table 39. Evaluation of tailored information booklet

Participant number	Positive comments	Negative comments
1	Useful, did not know that osteoporosis was asymptomatic before receiving the booklet. The image of osteoporosis was frightening but it was good to know that there were steps which could be taken to prevent further deterioration. She highly rated the diet section and reported that the size of the booklet was useful	
2	-	-
3	-	-
4	The image was useful. She found it useful to learn that a high alcohol intake was related	Did not feel personalised enough. She felt that on her image it was not clear that there were holes in the bones.

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Participant number	Positive comments	Negative comments
	to increased risk of fracture. She liked the dietary information	She did not like the terminology used in the dietary information, which she said was too Americanised.
5	The booklet was helpful	-
6	This patient reported that the leaflet was helpful and she wished she had been given it at the time of diagnosis. She said she felt that patients could manage their condition better with more information. She found the food list helpful	-
7	She said it was useful to know that a fracture is also known as a broken bone	-
8	The leaflet was helpful and the best part was the benefits and barriers to taking SR	The leaflet was too repetitive. The font was too small

10.4.2 What were the perceived mechanisms of the changes observed in adherence and/or psychological factors?

Participants were interviewed about the changes they experienced in their thoughts and behaviour as a result of the intervention. Ten themes relevant to this question are presented in Table 40 below and explored in the subsequent sections.

Table 40. Study 6 thematic analysis

Global themes	Themes
Pre-intervention thoughts and behaviours	Adherence
	Barriers to adherence
	Knowledge and understanding
	Medication side effects

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Global themes	Themes
Post-intervention changes	Changes in adherence/attitude towards adherence
	Future intention to change
	Changes in knowledge/understanding/perceptions of osteoporosis
	Changes in medication knowledge
	Changes in diet and exercise
	Post research barriers to adherence

Pre-intervention thoughts and behaviours

Participants discussed their adherence to SR prior to taking part in the intervention. Some participants reported little concern about missed doses. Participants also described barriers to taking SR prior to participating in the intervention, particularly their concerns about the medication and the difficulties experienced with fasting for four hours in order to take the medication as recommended.

Participants discussed their knowledge/understanding of osteoporosis and medication prior to the intervention. One participant suggested that she was in denial about having osteoporosis when first diagnosed with it, another participant suggested she had little knowledge of SR prior to the study. Some participants discussed their concerns about medication side effects they held prior to the intervention, as well as their concerns about SR and other medications they had previously been prescribed for osteoporosis.

Table 41 Pre-intervention thoughts and behaviours

Themes	Quotes
1. Adherence	<i>“Yes I was much more haphazard about it (SR) before... I was less committed to taking it really, I was forgetting more</i>

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Themes	Quotes
	<p><i>often.” (participant 3)</i></p> <p><i>“I took it because I’d been told to take it but if I missed one or two I didn’t really think about it too much.” (participant 6)</i></p>
2. Barriers to adherence	<p><i>“Before I had all these concerns and on top of that I, it was like this is what you’re supposed to do; take it, so I was resisting that, so I had a level of resistance... So before the research, I was really concerned about taking the medicine.” (participant 7)</i></p> <p><i>“I said that the problem from my point of view and apparently I’m not alone, is this 4 hour fast. I don’t have problems taking medication in any other way I mean I’m not somebody who is avert to medication or finds I can’t swallow tablets or anything it’s just that the 2 hours and then the medication then another 2 hours with my particular life style is really really difficult.” (participant 8)</i></p>
3. Knowledge and understanding	<p><i>“I suppose with osteoporosis at the beginning you think osteoporosis; that’s an old woman’s disease, but it isn’t, that’s the other thing I’ve learnt it isn’t.” (participant 1)</i></p> <p><i>“I knew a reasonable amount but I also didn’t know a lot about the medication I was given or why or how to interpret any of the bone scan results... Yea I didn’t feel that I knew really what this medicine was going to do for me, I didn’t know how valuable it was.” (participant 6)</i></p>
4. Medication side effects	<p><i>“I had first of all been given tablets to take one a week which made me feel</i></p>

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Themes	Quotes
	<i>really sick.” (participant 1)</i> <i>“It’s just that the medication that I’m on I had sort of doubts about whether they might cause other problems taking it, you end up with strong bones and everything else collapses around you!” (participant 2)</i>

Post-intervention changes

Many participants reported increases in their adherence and they provided some insight into what they believed was responsible for this change. Table 42 shows how participants varied in their perceptions of the mechanism of the changes they experienced during the intervention. Participants discussed issues of confidence, competence and fear reduction that were addressed in the intervention. Many participants reported increases in knowledge/understanding or perceptions of osteoporosis as a result of the intervention. Some participants reported no changes in their perceptions of osteoporosis or the medication. Post-intervention, some participants reported increases in knowledge about SR, particularly about the role of medication in reducing fracture risk.

Some participants reported changes in health behaviours other than adherence as a result of the intervention. When participants were asked whether they felt the intervention would continue to be beneficial to them after it was complete, some participants reported potential barriers to their future medication adherence. Participants also discussed their future intentions to change other health related behaviours post-intervention. This shows it is likely that the intervention gave participants a sense that they can take action to prevent fractures. The participant who refused to take her prescribed SR reported that she would not rule out other treatments developed for osteoporosis in the future, with less strict dosing instructions.

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Table 42. Post intervention changes

Themes	Quotes
1. Changes in adherence/attitude towards adherence	<p><i>"It made me realise how important it was, even though it doesn't sound very much to remember to take it every day, but I'm much more... what's the word... I make sure I take it every day rather than thinking I'll do it tomorrow."</i> (participant 1)</p> <p><i>"I feel more confident taking it now anyway, I haven't got the doubts in my mind that I might have had before."</i> (participant 2)</p> <p><i>"I think engagement and active engagement and understanding of the condition is an incentive for taking the medication now...I've realised now that it is very important, much more important than I had given it credit for. I'm much more compliant."</i> (participant 6)</p> <p><i>"It's only changed because of the research because you've allayed my fears; we've discussed all these fears and concerns."</i> (participant 7)</p> <p><i>"Sarah was very nice but persistent about how could we actually get me to take this retched stuff and because I felt committed to trying to be helpful I actually did get a regime going which I hadn't managed previously."</i> (participant 8)</p>
2. Future intention to change	<p><i>"My intention is to do a bit more exercise apart from my swimming."</i> (participant 1)</p> <p><i>"My next plan of action is to be much more diligent about my diet as well."</i></p>

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Themes	Quotes
	<p>(participant 6)</p> <p><i>"Well no only that you know I do, I have got in mind osteoporosis you know, that if anything came out that I would look at it again."</i> (participant 5)</p>
3. Changes in knowledge/understanding/perceptions of osteoporosis	<p><i>"The medication I've been given, there is only a 5 year window in which I can take it and I didn't know that and there's a lot of information I didn't know that I wouldn't have gleaned without the research."</i> (participant 1)</p> <p><i>"Yes, in that it's forced me to address my situation in a more committed way... I have to really face up to the fact that it is a problem whereas for a while I was just ignoring it really."</i> (participant 3)</p> <p><i>"I haven't really ever been too worried about it, I don't see that my bones are very weak or anything I know that it is only when you fall over that's when it happens, I have fallen over several times and I've had no problems so I have been lucky in that respect but I don't think it sort of changed my mind about it any way. I don't feel more worried or less worried about it."</i> (participant 2)</p>
4. Changes in medication knowledge	<p><i>"I thought that it probably does some good to the bones but as I mentioned before I wasn't sure what else it might do to you so that has really been sorted out through this research."</i> (participant 2)</p> <p><i>"It's given me, well it's given me lots and I was motivated because I didn't really understand the benefits of taking strontium ranelate I could only see the</i></p>

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Themes	Quotes
	<i>handicap.” (participant 7)</i>
5. Changes in diet and exercise	<p><i>“I’ve done a lot more walking let’s say.” (participant 1)</i></p> <p><i>“It is yes, so that is a definite change I’ve made so eating more oysters regularly and tahini instead of butter.” (participant 7)</i></p>
6. Post research barriers to adherence	<p><i>“Yea the other one is going to the doctors to get a prescription renewal, I must make sure that I do that in time as well.” (participant 1)</i></p> <p><i>“My GP is very concerned and doesn’t want me to take it but then what am I left with you see, I’m left in mid-air with no help for osteoporosis as such and the support needs to continue, it would have been good if Sarah’s study had continued a bit longer as its been left in mid-air at quite a crucial time.” (participant 3)</i></p> <p><i>“I will probably never get to taking it 7 days in a row and also because my GP was quite chilled about the necessity to take it full time but did pass me back to say as I’m under a specialist to follow what they say rather than what she is saying because she is not a specialist.” (participant 8)</i></p>

10.4.3 What was each participant’s subjective experience of taking part in the intervention?

Overall, the majority of participants reported that the intervention was a valuable experience for them. One participant felt that it had not helped her very much, although she could report some benefits for her participation.

Research interpretations

Participants were asked to describe what they believed the purpose of the research was. There were a range of interpretations, with the majority believing it was enable osteoporosis patients to self-manage their condition through better knowledge of both osteoporosis and SR. One participant identified the goal of the study as an investigation of compliance, whereas another participant believed the purpose of the research was to enable HCPs to have better knowledge of patients with osteoporosis. On the other hand, one participant was unsure of the study aim.

Given that participants invested a substantial amount of time and effort over the four month intervention period, participants were asked to describe their reasons for taking part. Motivation for participation can be divided into altruistic and personal reasons, with the majority indicating altruistic reasons. Some participants agreed to take part in the hope that the intervention would be of benefit to them, others said they wished to take part because they were supporters of the NHS. One participant discussed a mix of altruism and a will to start taking her medication. Some participants took part because they found the research topic interesting.

Participants were asked to describe the benefits and barriers of the intervention. The majority of participants reported a highly positive experience of being involved in the intervention. A commonly discussed benefit was the increase in understanding of the benefits of SR. Some participants reported that the research increased their awareness of the condition. Many participants commented on the benefits of having the opportunity to ask questions about their condition and medication. Some participants reported that they enjoyed the time and attention they received as a result of taking part in the research. However, one participant reported that she thought she had not benefited from the intervention.

Although not a direct consequence of taking part, participant 3 had a negative experience during the intervention period. Immediately after her MI session she reported feeling very motivated to take her medication and could list various reasons for wanting to reinitiate her medication. However, when she proceeded to ask her

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osteoporosis consultant for her prescription, she was asked to wait for 2 weeks before reinitiating SR, pending information from the MHRA regarding drug safety.

Participants reported the intervention was carried out over an adequate time period, because this allowed them sufficient time to absorb the relevant information. Participants valued the information booklet, particularly the list of foods containing calcium and magnesium. Participants were also pleased with ‘the benefits and barriers to SR’ section of the information booklet. Participants also reported that they found the images of osteoporosis included in their information booklets informative.

Participants pointed out a small number of negative aspects of taking part. The most common negative aspect discussed was the repetition of assessment questions, as well as some criticism of the assessment questions. One of the participants was confused that there were questions asking about symptoms when she did not experience any.

Table 43. Subjective experience of the intervention

Themes	Quotes
Research interpretations	<p><i>“I think, first of all it made me more aware of what it is, osteoporosis is, secondly and how it can be treated and the importance of taking medication.” (participant 1)</i></p> <p><i>“It’s about strontium ranelate and the benefits of taking it to manage osteoporosis.” (participant 7)</i></p> <p><i>“The purpose of the research was to look at compliance with medication and that’s how I understood it.” (participant 6)</i></p> <p><i>“Well I imagine two areas, one would be definitely from the point of view of osteoporosis and how one can partly prevent it, because Sarah was trying that as well, preventative, but also as well how one can heal it or improve it in a sense as well and how the medical profession and</i></p>

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Themes	Quotes
	<i>the health professionals can get more knowledge really of the patients and of this illness so to speak.” (participant 3)</i>
Motivation for participation	<p><i>“Well it was if it was going to help gage how the doctors and nurses and the consultants and so on should handle individuals with this condition... If I can help for that to be done in a good way for individuals who have got the condition.” (participant 4)</i></p> <p><i>“I wanted to see if I actually could get my head around taking it and doing that, secondly because I will back the NHS in doing research because I think that it is a good thing to do and it wasn’t too onerous, answering a few questions, I didn’t have to take medication.” (participant 8)</i></p> <p><i>“Well I was quite happy to help; I also found it beneficial really as I had certain doubts in my mind about the medication which has been sorted out now really because of that.” (participant 2)</i></p> <p><i>“I also didn’t know a lot about the medication I was given or why or how to interpret any of the bone scan results so when this project came along I had a lot of questions.” (participant 6)</i></p> <p><i>“Well I find all research.... I shouldn’t say all... I choose to take part in research that I would find interesting... I’m someone that enjoys taking part in research let’s say.” (participant 3)</i></p>
Benefits of research participation	<i>“I suppose the biggest thing was talking to Sarah about what the medication actually does to your body and how effective it can</i>

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Themes	Quotes
	<p><i>or can't be."</i> (participant 1)</p> <p><i>"I think that being on the research has forced me to take a little bit more responsibility in a way and to become more aware about my condition."</i> (participant 3)</p> <p><i>"I was forced to think about what I was doing much more and I was able to ask an awful lot of questions of Sarah and she was very very good and went off and found the answers which really helped me and so I think this has really helped me engage in a way with the condition and with treatment of the condition."</i> (participant 6)</p> <p><i>"In a sense having the support from the study... it's been like a mini counselling in sorts"</i> (participant 3)</p> <p><i>"There's a time factor that you spend with the consultant which was very brief and it is incredibly busy but to some extent this is the missing piece of the jigsaw in the whole process and I think that that has universal application across the whole NHS and I think it could be extended further."</i> (participant 6)</p> <p><i>"it was quite useful to me so from a selfish point of view it was useful, the other thing is again being the centre of attention the me, me, me bit, is quite nice when you've got research going on that you haven't just been abandoned to some old bit of medication that you've actually got someone taking notice and that's quite encouraging if you're taking something that you have slight concerns about."</i>(participant 8)</p>

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Themes	Quotes
Negative aspects of research participation	<p><i>“Not a lot... I found it very boring and a bit... repetitive and I went along with it in the hope that it was going to be helpful. It’s been of very little value to me personally but the more important thing is the greater good”</i>(participant 4)</p> <p><i>“I’ve been left with a lot of questions and some confusion, particularly from the medical profession...it’s also brought up an area of confusion as to whether this particular drug is actually going to help or not help!”</i> (participant 3)</p>
Positive aspects of intervention materials	<p><i>“The booklet that Sarah did was very very useful indeed and it was very nice that it was handbag size so that you could put it in your handbag because you could just pop it in your handbag and take it out if you wanted to get some shopping you think; oh well this would be good for... you know”</i> (participant 1)</p> <p><i>“It was the ‘benefits and barriers of your strontium ranelate’, that’s what I found was the most useful, it was at the back; the benefits of taking didle didle didle didley and then a whole list of things and then problems with taking it for osteoporosis, no immediate response, it can be difficult to fit it with medication, forgetting to take medication etc., etc., so there were very practical points.”</i> (participant 8)</p>
Negative aspects of intervention materials	<p><i>“It does have an impact because you think you are going to shrink and bend over and... not have a very straight back... that sort of image.”</i> (participant 2)</p> <p><i>“Oh yes the image is of bones with the holes in, you know, how it thins and you</i></p>

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Themes	Quotes
	<p><i>know how it can go to powder really sort of thing with osteoporosis yea... That was, you know, I knew that your bones went but I didn't realise they could go really holey... Yea because that was good yea because it told you without frightening you and shows you what happens."</i> (participant 5)</p> <p><i>"It does have an impact because you think you are going to shrink and bend over and... not have a very straight back... that sort of image."</i> (participant 2)</p>
Recommendations for future adherence interventions	<p><i>"Well I do think that going through the questions, the same questions on a regular basis that I found really quite extraordinary."</i> (participant 7)</p> <p><i>There were some things where it said agree, disagree, unsure and there wasn't a space to say... inappropriate... not relevant."</i> (participant 4)</p> <p><i>"But bits of the booklet were very repetitive and there were some things about the food which were quite American."</i> (participant 8)</p> <p><i>"The other thing is talking about symptoms of osteoporosis which I didn't have any... but I suppose that other people do, you probably have to put that in anyway because it's not just for me that questionnaire but I didn't have any symptoms at all so I was like; 'oh my god! Should I have some?'... Maybe the questions should say; if you do have symptoms the..."</i> (participant 1)</p>

Recommendations for future adherence interventions

Some participants gave some ideas for other types of adherence interventions which they thought might be beneficial for patients in the future. The suggestions were: a Frequently Asked Questions (FAQs) information sheet and also a patient support group.

“I mean I almost think that you need to get a full diagnosis and probably a Q and A sheet maybe several sheets when you receive the diagnosis and the prescription if you like so that you have all these answers I mean it’s not rocket science, how long has it been licensed? How long can I take this for?”(Participant 6)

“I’m not very good at these Facebook groups, but an opportunity for people to share their experiences.” (Participant 8)

10.4.4 Were participants satisfied with the intervention?

Overall, it is clear from the interview data that the majority of participants were satisfied with their experience of the intervention. Four of the eight participants spontaneously contacted the author after the study was completed to say that their participation in the intervention had been valuable for them. Table 44 shows the result of the questions assessed using Likert scales. Participant 4 was unsatisfied with the research, largely because of the repetitive nature of the questionnaire data collection. Participant 3 was only moderately satisfied, which she attributed to her experience of being asked to wait before reinitiating her medication.

Table 44. Participant satisfaction with the intervention

Participant	1	2	3	4	5	6	7	8
Satisfaction*	5	5	3	2	5	5	5	5
Would you recommend the intervention to a friend?	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes

*The scale was 1-5 with 5 indicating high satisfaction

10.5 Discussion

10.5.1 Summary of key findings

The detailed process evaluation of the overall intervention indicates that it was effective and well accepted by the majority of this group of patients. Participants were able to provide their accounts of the potential mechanisms that resulted in increased adherence. The results of the framework analysis showed that the reported mechanisms of change varied between participants. When participants were asked directly about the mechanisms of any changes, the following were the most salient:

- Monitoring
- Increased understanding of the condition
- Increased understanding of the importance/necessity or benefits of SR

Other mechanisms patients discussed included acceptance of having osteoporosis and having their concerns about osteoporosis medication addressed.

The intervention appears to have increased adherence through different mechanisms for each participant. This provides support for selecting a multi-faceted intervention. However, it should be noted that these are patient's opinions of change which may not reflect the underlying mechanisms of behaviour change. Their responses are possibly subject to response bias and it is possible that participants were unable to account for the exact mechanisms of change. However, responses were in agreement with the outcome evaluation data from study 5, which demonstrated an increase in perceived coherence for all participants, as well as an increase in the perceived need for and the efficacy of osteoporosis medication.

Consistent with an observation in the previously presented qualitative project (study 2), patients had a large number of questions about their osteoporosis and the medication. It is evident from the process evaluation that patients highly valued the opportunity to ask questions (which were referred to a medical specialist if required). This educational component of the intervention provided patients with space to think

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about the questions they had about their condition. It also provided the opportunity to open up a channel of communication between doctor and patient. Patients who asked more questions engaged better with the intervention. One patient asked a very long list of questions about the condition and relevant medication and at the end of the study reported high satisfaction with the intervention and that it was a luxury to have had all her questions addressed. The finding that patients valued the opportunity to ask questions has implications for clinical practice. It appears patients need more time with healthcare professionals in order to ask questions.

Many participants commented on the size of the information booklet, which was A5. They reported that the size enabled them to carry the booklet in their handbag and refer to it when they needed. The finding that participants valued this detail of the intervention was interesting, considering that the booklet size was the suggestion of one of the expert patients involved in the study design. This provides support for the value of including expert patients at the study design stage, which in turn can help to make the intervention more convenient and acceptable for patients.

At the end of the study, patients were asked if anything else had happened during the intervention period which may have altered their medication-taking. All patients who increased their medication-taking attributed this change to the intervention. An important issue is whether the assessment acts as a kind of monitoring intervention, where a patient changes their behaviour because they know they will be questioned about adherence. It would be worthwhile to replicate this study with fewer points of assessment to remove the possible effect of monitoring. Removing the monthly assessments would also make the intervention less time consuming.

Another important question is; could this research be delivered over a shorter time span, perhaps over the telephone? The evaluation data strongly suggested that patients were pleased with the amount of time devoted to this intervention and valued the amount of space between each element. Further, they reported that they believed they benefited from the face-to-face session. Although it could be more

time/cost effective, it appears it would be unadvisable to remove these elements of the intervention.

An important strength of this process evaluation was the employment of an independent assessor, who neither designed nor delivered the intervention. The independent assessor interviewed participants and analysed the data to control for bias at all stages of the project. This is of great importance, because it removed the potential bias which would be highly likely if the evaluation was carried out by the author, who may have had an emotional attachment to the intervention. The result of this was a well-balanced evaluation of the intervention. A further strength was that an effort was made to ensure that patients received the intervention as intended, which has been recommended as good research practice (Bellg et al, 2004). This was achieved by a follow-up phone call to check whether patients had understood the educational material they were sent and whether there were any questions.

10.5.2 Suggested improvements for future adherence intervention design

- Include an information sheet with FAQs about osteoporosis and relevant medication
- Make the information booklet more tailored
- Select patients based upon their total barriers score from the DOTMQ as well as MARS (discussed in previous chapter)

To reduce the time spent researching answers to patients' questions about their illness and medication, a participant suggested it might be beneficial to provide osteoporosis patients with a FAQs information sheet. This information sheet could perhaps be designed based on questions and answers generated from this study. However, this removes an element of tailoring from the ATOM study which may have been an effective ingredient.

One participant reported that tailoring was not important. Another participant commented that the tailored information booklet did not feel tailored enough. For example, in the section about personal control, it was recommended to all patients to

avoid smoking. One participant suggested removing this, or for people who have quit smoking, to commend them for this effort. Perhaps the way in which the information was tailored should have been more highly emphasized. It should be noted that perhaps the effects of tailoring the informational booklet were not highly visible to the participants, because they were not aware of the detailed method used to select information for each of their booklets or how their own booklets differed from those of other patients.

10.5.3 Limitations

It is possible that the results were affected by social desirability bias, in that patients knew the objective of the study was to improve adherence, so they demonstrated that they improved when in fact they did not. A possible example of this was evident from one participant's dialogue who suggested at the beginning of the intervention: 'I will be one of your success stories.'

A factor which could be regarded as both an advantage and disadvantage was that many participants reported that the author (who delivered the intervention) and the independent assessor (who assessed the intervention) were reliable and pleasant to work with. While this can be seen as a study strength in terms of researcher professionalism and patient satisfaction, there is an issue as to whether the effectiveness of the intervention could be attributed to the nature of the researchers to some extent. To control for this in future, it is recommended that participants are asked to record the warmth of the researchers, so that it can be ascertained whether this factor predicts the outcome under investigation (Bellg et al, 2004). This is particularly the case for interventions which are delivered by more than one researcher or health care professional.

A challenge for process evaluations is to differentiate between the effects of the intervention (e.g. education or motivational intervention) and the research (assessments using questionnaires). However, it is not possible to separate the research from the intervention using the case study approach and indeed some participants discussed the monthly assessments as an element which

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encouraged/reminded them to take their medication; indicating that monitoring may in fact have become an effective ingredient of the intervention. It would be informative to test this intervention in an RCT which would have a control group who receive the assessments but not the intervention.

The process evaluation interview schedule did not include a question to assess any unwanted effects of the intervention. It was hoped that any unwanted effects could be assessed from the evaluation of the outcome data from the study 5 assessments. Negative responses to visual images of osteoporosis were thoroughly explored in study 4.

10.6 Conclusions

Overall, there is evidence to suggest that different elements of the intervention were effective for each participant. Mechanisms that increased adherence were suggested by patients to be:

- *increased understanding of the importance and benefits of SR for osteoporosis

- *increased perceived understanding of the condition

- *monitoring

- *addressing concerns about the medication

The data also indicates that increased attention and the opportunity to ask questions about the condition and medication may have been key elements resulting in the increased adherence observed in study 5. While patients found the regular assessments tedious, they reported a very positive subjective experience of taking part in ATOM intervention, with the majority reporting high satisfaction. However, future work is needed to test whether the ATOM intervention (tailored education, motivational interviewing, plan setting and telephone follow-up) was effective when independent from the research (monthly assessments of psychological factors and adherence).

11 General Discussion

Chapter overview

The overall objective of the research presented in this thesis was to develop and test a psychological intervention to improve adherence to osteoporosis medication. This final chapter will describe some of the theoretical and methodological contributions to the knowledge of patients' adherence to osteoporosis medication. The MRC's framework for the design and evaluation of complex interventions was used to guide a series of intervention development studies, to provide a theoretical underpinning for the ATOM intervention. The critical review enabled the identification of a strong evidence base concerning the link between psychological factors and adherence to osteoporosis medication. The subsequent intervention development studies enabled further insight into how patients view their condition and the reasons for low adherence in this population. As each study chapter included a detailed discussion of the findings, this chapter will draw together these findings and give a summary of the unique contributions of the present research.

11.1 Summary of studies

To assist readers to follow this general discussion, a summary of each study along with the study number is provided.

Table 45. Summary of the intervention development studies presented in this thesis

Study number	Title of study	Research design
Study 1	The psychological factors in non-adherence and non-persistence with osteoporosis medication; a critical review	Literature review
Study 2	How do osteoporosis patients perceive their condition and	Qualitative interview study

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Study number	Title of study	Research design
	medication?	
Study 3	The psychological factors related to osteoporosis medication adherence	Cross-sectional, questionnaire study
Study 4	Osteoporosis patients' ratings of five visual images of osteoporosis	Cross-sectional, questionnaire study
Study 5	A multifaceted intervention to increase adherence to osteoporosis medication: a case-series approach	Intervention, a series of case studies
Study 6	Process evaluation of a complex behaviour change intervention to increase adherence to osteoporosis medication	Qualitative interview study

11.2 Contributions to knowledge about the psychology of osteoporosis medication adherence

The critical review (study 1) provided some useful insights into previous research which investigated the relationship between psychological factors and adherence to osteoporosis medication. Knowledge, medication side effects and medication beliefs were the common focus of much previous research about the determinants of adherence. The review enabled the identification of gaps in the literature, with very few studies investigating osteoporosis patients' illness perceptions and risk perceptions and no studies investigating whether individuals' emotional responses to having osteoporosis influenced their medication adherence. Perhaps the most important finding was that with the exception of the necessity-concerns framework, studies did not utilize health psychology theories to guide the investigation of the

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relationship between psychological factors and adherence. This review indicates that it is well established that psychological factors are related to osteoporosis medication adherence, particularly knowledge, medication side effects and concerns about medication. The following studies provided insight into other psychological factors which are implicated in osteoporosis medication adherence, with motivation and self-efficacy as the strongest predictors of the factors investigated.

Studies 2, 3 and 5 demonstrated that osteoporosis patients have a wide range of illness and medication beliefs associated with their condition. These individual differences suggest that tailored interventions would be beneficial. A common reason patients gave for not taking their prescribed osteoporosis medication was that they did not fully understand its benefits (studies 2 and 6). While this supports the findings of previous research (Ringe et al, 2003), it goes further to suggest that patients specifically do not understand that the goal of medication for osteoporosis is to reduce the associated risk of fragility fracture (study 2).

The ATOM intervention consisted of several novel dimensions, including the use of psychological theory to inform the intervention design, the tailoring of educational materials for individual patients and the use of a detailed process evaluation (studies 5 and 6). In addition, the study investigated patients' drawings of their condition as well as interpretations of their drawings. There were overlaps in the findings of the outcome and process evaluation of the intervention (studies 5 and 6). They both indicated similar possible mechanisms underlying the increases in adherence demonstrated in the ATOM intervention. Table 46 shows the mechanisms of behaviour change as indicated by each study.

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Table 46. Successful mechanisms for increasing adherence

Psychological construct	Outcome evaluation (study 5)	Process evaluation (study 6)
Increased perceived coherence	✓	✓
Increased perceptions of treatment control	✓	✓
Increased beliefs in the necessity of the medication	✓	✓
Monitoring	-	✓
Social Support	-	✓

A key finding of the intervention process evaluation (study 6) was that patients valued the opportunity to explore the benefits of and barriers associated with strontium ranelate. It seems that acknowledging the barriers to adherence was helpful for patients, perhaps because this provided them with a well-balanced argument enabling them to make an informed decision about their medication. A likely mechanism of change (the increases in adherence observed in the intervention study) was partly due to the patients being better informed about the specific role of their medication in the reduction of fracture risk.

It is important to note that while the above mentioned mechanisms applied to the majority of the group, the study 6 data indicates that different components of the intervention were effective for each individual. In the intervention process evaluation, one participant described that allaying her concerns about the medication was the key ingredient which enabled her to take her medication, though other participants did not mention this. Concerns were addressed via the question and answer element of the

psycho-educational component of the intervention, in which many participants inquired about the safety of the treatment for long-term use. Some participants described the effects of monitoring and social support, while others did not. The tailored elements of the intervention are likely to be responsible for the intervention effectiveness. Details of how the educational materials were tailored are included in the methodological contributions section.

11.3 Theoretical contributions

The use of psychological theory provided a systematic method for designing and testing a behaviour change intervention to promote adherence. This is the first study to use a combination of the extended Self-Regulation Model (SRM) and the Extended Parallel Process Model (EPPM) to inform an adherence intervention for osteoporosis patients. The research included in this thesis provides support for using the Information, Motivation and Behavioural (IMB) skills model (Fisher & Fisher, 1992) to guide the selection of behaviour change techniques. Study 3 found that motivation and self-efficacy were significant predictors of adherence to osteoporosis medication. These findings are congruent with the IMB model. The resultant intervention appears to have been successful, though future work with a larger sample is required to ascertain whether the results observed were due to chance, or factors outside the actual intervention components.

All six studies presented in this thesis provide support for Leventhal's SRM (Leventhal et al, 1984). While it might be expected that this model was most appropriate for symptomatic conditions, the work presented in this thesis demonstrates the utility of the model for osteoporosis which, until the later stages, is largely an asymptomatic condition. There is clear support for the SRM in the ATOM intervention outcome data (study 5), where there were many fluctuations in psychological factors, indicating that these factors are dynamic in nature. Although perceived coherence was not a significant predictor of adherence in the univariate analysis (study 3), the results of the outcome and process evaluations indicate that when patients have a coherent model of their illness, they are more likely to take their prescribed medication. Further,

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perceived coherence increased for all of the study 5 patients, as did adherence for all but one. The extended SRM variables explained a small but significant amount of the variance in adherence to osteoporosis medication.

Further, this thesis supports Witte's EPPM (Witte, 1992). Some participants in study 6 commented that the image of osteoporosis presented with efficacy information for how to reduce the risk of osteoporotic fracture was beneficial, helping them understand the severity and how to manage it. The EPPM variables explained a significant amount of the variance in adherence to osteoporosis medication. There was no increase in patients' emotional responses to the condition during the intervention, this could be attributed to the use of the EPPM to guide the intervention design, in so far as providing both threat and treatment efficacy information. There is further support for the both the SRM and the EPPM in study 4. Osteoporosis patients' ratings of depression and worry were significantly related to their adherence, perhaps indicating that a high emotional response leads to emotion focused coping/fear control rather than problem focused coping/danger control.

However, there were some discrepancies in relation to findings of whether emotional response was related to adherence. The discrepancy was between the findings of studies 3 and 4, where in study 3 emotional response was not related to adherence, but in study 4 depression and worry had a small but significant association with adherence. Perhaps this discrepancy can be explained by the different methods of measuring emotional response. More research is needed with a larger sample size and a longitudinal focus to determine the strength and direction of the relationship between adherence and emotional responses to osteoporosis.

Factors from both of the theories investigated predicted adherence to osteoporosis medication (study 3). While these theories have proved useful in the design of an intervention to promote adherence to osteoporosis medication, it should be noted that they did not provide a complete explanation of adherence behaviour. When these models were combined, they explained 35% of the variance in adherence behaviour. This indicates that there are gaps we still need to understand and this informs us that

there are factors not included in the theories which should be included in adherence interventions. Other possible factors which may account for further variance in adherence include: HCP-patient communication, past behaviour, unconscious thought processes, social/cultural factors, social support and mood.

A further theoretical contribution was the adaptation of Normalisation Process Theory (NPT) (May & Finch, 2009) to evaluate individual behaviour change. This model was useful because it enabled an exploration of the mechanism of change. Importantly, study 6 showed that the mechanism of change varied widely between participants.

11.4 Methodological contributions

There were many methodological contributions in the present research. Although this was not the first study to use the MRC's framework (Campbell et al, 2000) to design an adherence intervention, it was the first use of this framework to design an intervention for patients prescribed with oral medication for osteoporosis. The studies included in this thesis provide good evidence for using the MRC's framework, given that it resulted in an intervention which increased adherence for seven out of eight osteoporosis patients. It proved to be important to assess the psychological factors related to non-adherence to medication, because when these factors were targeted in an intervention, the intervention had a positive effect on adherence. Similar results were found in another adherence intervention, which used the MRC's framework to create an effective intervention to increase stroke patients' medication adherence (O' Carroll et al, 2013). The present research and the research carried out by O'Carroll et al (2010; 2013) indicates that a project following the MRC's framework for the design and evaluation of complex interventions enables the psychological constructs relevant to adherence to be identified and addressed.

As far as the author is aware, this was the first study to use an N-of-1 case-series design to investigate low medication adherence in osteoporosis patients. The use of this approach was beneficial because it allowed the measurement of many psychological factors with participants at multiple time points, as well as an in-depth evaluation of the intervention with the entire study sample. Useful results were

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revealed by using this case study approach. However, some things are still not clear. It is still unknown why the intervention did not work for one of the patients. Although there is some evidence to suggest the ATOM intervention could be beneficial for roll out in the NHS, a much larger sample and study time period is required to assess the long-term effects. There is a strong indication that the ATOM intervention was effective in increasing adherence for seven out of eight participants which provides an evidence base for testing this intervention with a larger sample.

A novel contribution from the present research was the design of a systematic method of assessing patients' health informational needs and tailoring educational material. To diagnose patients' information needs, they were assessed using questionnaires and their scores indicated the medical information they required or did not require. They did not require medical information for questionnaire items when their scores indicated understanding of a particular element of osteoporosis or strontium ranelate. This was the first study to use this type of methodology for tailoring information using the extended SRM and the EPPM. This method enabled the diagnosis of patients' informational needs to guide the selection of educational information to meet these needs. There is evidence to suggest that this method was successful when considering the increases in adherence and perceived coherence observed in study 5. However, it is necessary to compare tailored and non-tailored educational materials for osteoporosis patients in a randomised controlled trial before concluding that tailored educational materials are beneficial.

Two questionnaires were developed as part of the present research, the Difficulties Of Taking Osteoporosis Medication Questionnaire (DOTMQ) and the Osteoporosis Images Questionnaire (OIQ). The DOTMQ has proved to be a useful measure of participants' barriers to taking their treatment. Interestingly, it was found the DOTMQ score was more indicative of patients with low adherence than the MARS score in study 5. Perhaps the barriers score provides a proxy measure of adherence. Another possibility is that the DOTMQ provides a better indicator of adherence because it is a more covert measurement. The OIQ enabled the capture of data regarding patients' ratings of

visual images of osteoporosis. This is a novel method of assessing patients' responses to the condition.

11.5 The contribution of drawings and images of osteoporosis

Patients' drawings of osteoporosis were used as a tool for gaining insight into patients' perceptions of osteoporosis, as well as their response to the ATOM intervention. To the author's knowledge, for the first time it was demonstrated that osteoporosis patient's drawings of their condition can provide insight into how they view their condition (Besser et al, 2012). Patients' narratives about their drawings appeared to reveal emotional responses to the condition which were masked during the interview conversation, though more research with a larger sample would be ideal to explore this further. However, these results suggest that the use of drawings provided access to some unconscious thoughts/emotional responses to the condition.

Given that drawings seemed to access masked emotions, osteoporosis patient's responses to images/pictures of osteoporosis were explored in further detail in study 4. This was carried out to explore the potential of images of osteoporosis as adherence intervention materials, or whether they produced negative effects on patients. While there were mixed results, the majority of participants welcomed the opportunity to be presented with an image of their condition, which was expected in a condition which is asymptomatic and therefore invisible to the patient. The qualitative analysis of patients' responses to images (study 4) suggested that many patients found the images informative and motivational, therefore it was decided it would be beneficial to include them in an adherence intervention. One of participants declined to complete the OIQ in study 4, reporting that she would find the images too pessimistic. Therefore this patient was not provided with an image in her tailored information booklet in study 5. This, together with the range of participants' responses to each different image of osteoporosis provided evidence for selecting different images for each patient in the intervention study. The results of the intervention process evaluation (study 6) imply that images of osteoporosis may be effective in helping patients to understand the risks in osteoporosis and the overall study indicates that tailoring the

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choice of these images is important, though more work with a larger sample is required.

As far as the author is aware, this was the first study to assess osteoporosis patients' visual representations before and after an adherence intervention. In both studies which included drawing as a research method (studies 2 and 5), there were differences in the sizes of drawings made by participants in different groups or stages of the intervention. These size differences are interesting, particularly given that the size of drawings could be related to the salience of the problem to the patient (Broadbent et al, 2006a). Of particular interest was the finding of pre-and post-intervention size differences for participants whose adherence increased, but no size difference for the participant who showed no change in adherence behaviour. It seems that using drawing to explore patients' response to osteoporosis accesses a different medium of expression.

11.6 Patient and public involvement

Following good research practice, patients and the public were involved in several stages of the research process, including the design of the research. Before beginning this project, a member of staff at the National Osteoporosis Society was contacted to find out whether the topic of adherence to osteoporosis medication was a priority for them. Two patients with osteoporosis were involved in the design of the overall PhD project idea, to check that this is something important and relevant to patients. The use of Patient and Public Involvement (PPI) in the present research is a strength that was confirmed in the evaluation of the intervention, where patients valued the elements suggested by the expert patients. The following table shows the activities expert patients and service users participated in for each study.

Table 47. Patient and Public Involvement in research

Study number	PPI members	Activities involved in
2	Expert patients	*Study design *Interview schedule

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Study number	PPI members	Activities involved in
		development *PIS *Consent form *Pilot of drawing exercise *Pilot interview
	Service Users	*Interview schedule design
3	Expert patients	*PIS
4	Expert patients	*Image Questionnaire design
5	Expert patients	*Study design *Information booklet design
6	Service users	*Information booklet design

As well as involving patients and members of the public in the study design, the author presented this research at various conferences. A further method of public engagement was when the author presented the problem of adherence to medication at Speakers Corner in Hyde Park, London, as part of a public speaking course. This enabled the author to gain some insight into the views of the general public about the problem of low adherence to medication in chronic conditions. Some reflections of this are provided in the overall conclusions section.

11.7 Limitations

The limitations specific to each study were presented in the discussion section of each chapter. This section will provide some general limitations which are applicable to the majority of work presented in this thesis. The issue of using self-report measures of

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adherence should be addressed, because of the bias involved, particularly when collecting this data retrospectively. Self-report is likely to provide an overestimation of adherence. Both reports from doctors in clinical practice and comparisons of self-reported data with Mean Possession Ratio (MPR) data confirm this (Ziller et al, 2011). The defence for using self-report measures is that there is no accurate or gold standard measure of adherence, however, self-report is the most practical. In an attempt to overcome presentational bias, three measures of self-report were used so that the data could be compared.

Considering that men are known to seek-help less frequently than women in relation to health related issues (Weissman & Klerman, 1977), it is important that future research investigates adherence in males. The reason for excluding males from this study was the low number of male patients diagnosed with osteoporosis, which would have made recruitment to the study difficult. In view of the high number of factors being explored in this research, excluding men enabled a reduction in the number of study variables. It is possible that men and women have different common sense models of their illness, with different psychological factors explaining adherence. Other studies have investigated the way in which men with osteoporosis understand and make sense of their illness. Solimeo et al (2011) found that for men a particular barrier to adherence was concerns with the safety and efficacy of osteoporosis medication for men, because of their awareness that many clinical trials of osteoporosis medication were carried out with female osteoporosis patients, due to the low ratio of male to female osteoporosis sufferers.

Another methodological problem is related to the drawing part of the intervention assessment. The participants who received the ATOM intervention (study 5) had already seen some images of osteoporosis for study 4 and their depictions of osteoporosis were likely to be influenced by these. A final important limitation was the use of a cross-sectional design in study 3, given that this design does not allow identification of the direction of causality. However, the cross-sectional design was suitable for the purpose it served in the intervention development.

11.8 Overall conclusions

The research presented in this thesis suggests that future interventions to improve osteoporosis medication adherence could benefit from using a refined version of the ATOM intervention. This method of designing an intervention appears to have been effective in changing psychological factors and increasing adherence, though more research is needed. Given that the intervention was effective and satisfactory to patients, the next step is to carry out a further trial of this intervention, to assess whether the changes observed were statistically significant and to investigate its utility in various settings. However, a much longer intervention follow-up period is required in order to determine whether the increase in adherence has an impact on fracture risk, as well as whether the changes in medication-taking behaviour are sustainable in the long-term.

It was apparent that many patients required additional information and support in order to be able to self-manage their osteoporosis effectively. Overall, the research presented in this thesis provides an argument for the use of health psychology expertise in the design of behaviour change interventions in order to support patients with self-management of chronic medical conditions. The argument is justified by the many misconceptions patients had about their illness and medication (in studies 2 & 3, 5 and 6), as well as the various questions they asked about their condition and medication (studies 2 and 5). More psychological and informational support is paramount to empower osteoporosis patients to effectively self-manage their condition. There is also a role for health psychologists in the provision of training for doctors, nurses, pharmacists and other key health professionals in relation to how to deliver adherence interventions.

Much of the work presented in this thesis shows that managing a complex chronic condition such as osteoporosis can be very challenging. On reflection, overall the interviews in study 2 indicate that osteoporosis is a condition of many confusing inconsistencies about self-management for its sufferers: on one hand, osteoporosis patients are asked to have a high calcium intake, on the other they are reminded to keep their cholesterol levels low by eliminating cheese and milk from their diet; they

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are required to obtain vitamin D from exposure to sunlight, but to avoid developing skin cancer; they are encouraged to engage in weight bearing exercise to strengthen their bones, yet prevent themselves from falls to avoid fractures. Hence, osteoporosis sufferers need to continuously weigh up the risks associated with osteoporosis against those of other medical conditions. These mismatches in health advice may play a part in explaining non-adherence in patients with osteoporosis. It seems that this is an important part of the story of why some osteoporosis patients may be non-adherent to medication or other lifestyle recommendations. The qualitative studies (studies 2 and 6) indicate that patients need much more information about their condition, particularly the risks involved. There is evidence that patients have feelings of denial about the condition and avoiding anything to do with osteoporosis, which was derived from both qualitative studies.

It is important to note some problems which are related to the complexity of the adherence problem. Adherence to medication does not always lead to the desired improved health outcome. Some patients may do not respond to their medication even if they are adherent and some classes of medication can result in additional medical problems (e.g. the use of steroids for various medical conditions can lead to osteoporosis). Promoting adherence is only acceptable and of benefit when the prescription is correct. A significant event that occurred during the course of this doctoral research was that during the delivery of the ATOM intervention (study 5) it was announced that strontium ranelate was not a safe treatment choice for osteoporosis patients with coronary disease because it might increase the risk of myocardial infarction (MHRA, 2013). A participant involved in study 5 suffered with high blood pressure. She initiated strontium ranelate during the intervention, however, she and her health care professionals were unaware of the potential danger it was causing, because of her pre-existing cardiovascular condition. This shows how medication can be harmful to patients even though the harmful effect is not known at the time of prescription. There can be adverse effects on patients which are not yet realised.

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Although there is strong evidence to suggest that adherence to prescribed medication in general results in better health outcomes, a group of HCPs was found to have sub-optimal medication adherence (Ley, 1988). This perhaps shows that knowledge of medication is not the only contributing factor to low adherence. Another interpretation of this low HCP adherence is a possible general level of scepticism about the effectiveness/safety of medication, which is apparent in previous and the present research (e.g. Horne 1997). There was evidence of distrust of pharmaceutical companies in the present research. One of the participants who took part in the adherence intervention described how she thought she had a healthy scepticism about medication and some participants from study 2 made similar comments. Further, there are recent examples of pharmaceutical companies making unjustified profits from the sale of medication (Bryant et al, 2013). When pharmaceutical companies are concerned with money and profit, it is not surprising that individuals will question whether these companies have their best interests at heart. Every effort should be made to ensure that patients are well informed about their healthcare choices and the research/evidence that lies behind these treatments.

When the present research was presented at Speakers Corner, some members of the public argued that interventions to improve adherence could be seen as health fascism. It should be noted that the aim of adherence interventions is to give patients the chance for informed adherence (Horne et al, 2005). This is the opportunity to have a clear understanding so that the patient can make an informed decision in relation to how to manage their health. This is where motivational interviewing has its strength in adherence interventions, because it is focused on helping a patient to explore their own motivation for taking medication.

The change in the terminology used to describe medication-taking is interesting. The term has shifted from “*compliance*” to “*adherence*”. Could changing the terminology used to describe medication-taking behaviour have an effect on adherence to treatment? The idea of a shared agreement between a doctor and their patient or shared decision making could leave the patient more open to deciding not to take their treatment, rather than if they were told that they need to take it. It could cause

confusion for patients who are not aware of this shift in healthcare control. Further it is likely that the term “compliance” was never about doctors telling patients what to do against their will. The usefulness of this change in terminology might be questioned, particularly when the term “adherence” has not been adopted in clinical practice and adherence rates have not improved. In an attempt to address concerns around the terminology used to describe medication-taking, the term “*concordance*” was suggested to signify agreement between a HCP and a patient about therapeutic goals. This term has not been universally adopted and is often used in error as synonymous for adherence (Horne et al, 2005). A further reflection is that the term *adherence* is too strong, because although it was suggested as a replacement of the term *compliance*, it still implies that the healthcare professional is in control when in fact the patient is in control in terms of self-management. I would recommend that health care professionals and researchers replace the term again from adherence to *medication-taking*, which implies no blame on either the patient or the healthcare professional.

A final reflection is that although there is a multitude of research projects investigating the factors related to non-adherence in many medical conditions, there is relatively little happening at the front line of healthcare to promote adherence. The results of the intervention process evaluation (study 6) indicate that there is a need for better information for patients about their illness and medication. As well as information there is a need for better communication and delivery of information about health. This is a practical role that health psychologists could undertake with osteoporosis patients, as well as in a wide variety of other healthcare specialities.

11.9 Future work

Although there was an increase in adherence in the ATOM intervention study, the positive result should be taken with caution and there is a need for future work to determine whether the intervention is as successful with a larger sample. Before progressing to an RCT, the next step could be to conduct a study comparing the intervention group to a control group who receive usual care. Future developments of the intervention could test which behaviour change techniques are the most suitable

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to modify each psychological determinant of adherence (Michie et al, 2008), e.g. is psycho-education the best intervention to increase patients perceived need for medication? It would be beneficial to develop the intervention, including some of the suggestions of the participants in study 6.

Although the present study indicates that tailored educational materials were a successful element of the ATOM intervention, more knowledge of the effectiveness of tailored materials is needed. To progress knowledge in this area, it would be beneficial to conduct an RCT to compare adherence in three groups: a group who receive tailored educational materials, a group who receive educational material which is not tailored and a control group who have assessments of adherence only.

Further work is needed to ascertain whether the results of the drawing exercise, particularly the smaller size of bone drawings post-intervention in comparison to pre-intervention, were statistically significant. To develop research of depictions of osteoporosis, it would be interesting to approach the drawing exercise differently. Rather than asking patients to draw how they visualise bones and people with and without osteoporosis, it would be interesting to ask them to simply draw how they visualise osteoporosis, in order to investigate what aspect of it they would draw.

The present research provided patients with information about diet and exercise which was well accepted. The ATOM intervention could be adapted to promote adherence to diet and exercise recommendations. Before designing other types of non-pharmacological interventions, more knowledge is needed regarding non-pharmacological treatments for osteoporosis, e.g. diet and exercise interventions and their effects on bone health. While there has been much research about the role of calcium in bone health, more research is needed to determine the effects of other minerals such as magnesium and potassium, as well as vitamins B, C and K (NOS, 2013), which are expected to be important in maintenance of the skeletal system. Although it is known that magnesium is important for a multitude of health benefits, including strong bones, there is currently a lack of research as to whether it is as important to bone health as calcium and vitamin D supplementation. A recent study

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indicated that magnesium may be as important as calcium, if not more so for increasing bone mineral density in children (Abrams et al, 2013).

Overall studies 5 and 6 indicate that the ATOM intervention is likely to be successful in increasing adherence. Prior to the implementation of this intervention on a large scale, the intervention will need to be tested against a control group. Importantly, the intervention should be fully powered and based at various sites. An important factor in the implementation of ATOM is to determine the optimal healthcare setting for the intervention delivery. To gain insight into which setting this intervention would be best placed within the NHS, it would be beneficial to test the feasibility of the intervention in a variety of healthcare settings, including primary care and pharmacy. The pharmacy may be a particularly important point of care, considering that this is the place where the patient receives their medication and may be thinking about how they will use it. Further, it may be beneficial to develop the intervention for use with patients with other chronic conditions.

To translate the intervention into practice, health psychologists could be involved in both the delivery of the intervention and in the training of other healthcare professionals (e.g. doctors, nurses and pharmacists) in how to deliver adherence interventions. In the future, in the author's opinion, it would be beneficial if all healthcare settings were able to draw on health psychology expertise. Knowledge from health psychology could be used to promote self-management of chronic conditions and to improve service delivery. This would improve the quality of the healthcare service, based upon some of the comments from patients in study 6. As well as increasing patients' satisfaction with the service, better self-management may also improve patients' health outcomes.

The logic of using the MRC's framework for the design and evaluation of complex interventions is to build on each stage of intervention development, as the evidence of the interventions effectiveness increases. Therefore a recommendation for the next stage of the ATOM intervention development is a small trial with an intervention group and a control group, before progressing to an RCT. Based upon the present research,

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the recommendations for the future development of the ATOM intervention are provided below.

Study features recommended for the next stage of intervention development

- A control group consisting of patients who have usual care with assessments of adherence only
- A comparison of tailored and non-tailored educational materials based upon the extended self-regulation model and the extended parallel process model
- Assessment of emotional responses to osteoporosis and their relationship with adherence
- Use the DOTMQ questionnaire to ascertain the number of barriers to adherence each patient experiences. Deliver the intervention to those who report a high number of barriers > 2 and a MARS score < 23
- Rather than collecting and addressing patients questions about their condition or medication, a FAQ information sheet about osteoporosis and medication could be used to address patients concerns
- Long-term follow-up to assess outcome variables: 3 months, 6 months and 1 year post-intervention
- Include both male and female osteoporosis patients
- Test an adaptation of the ATOM intervention for improving adherence in other chronic and asymptomatic medical conditions
- Test an adaptation of the ATOM intervention for promoting diet, exercise and falls prevention for osteoporosis patients
- Test the ATOM intervention in a variety of healthcare settings, e.g. pharmacy and primary care

11.10 Concluding remarks

Osteoporosis is a prevalent and serious condition, with considerable risks if left untreated, particularly if patients fail to make the best use of their prescribed medication. The work presented in this thesis attempted to gain a better understanding of why many patients with osteoporosis do not adhere. It has also attempted to use this understanding as a basis for a novel intervention, to help patients make an informed decision about their medication, as well as to provide guidance for how to prevent unintentional non-adherence such as forgetting. It is hoped that this intervention development study can be progressed to the next stage of development in future research.

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Appendices

APPENDIX 1. Search Strategy (study 1)

Osteoporosis (osteop*)

and

adherence (adheren* or non?adheren* or persist* or non?persist* or complia* or non?complian* or 'patient?compliance' or 'non?fulfilment' or 'medication adherence' or 'medication?use' or 'drug?use' or 'medication?taking' or 'mean possession ratio' or 'medication possession ratio')

and

predictor (predictor* or factor* or determinant* or 'Illness?perception*' or 'illness?belief*' or 'illness?representation*' or 'illness?schemata' or belief* or 'treatment?belief*' or knowledge or medication?belief* or thought* or cognit* or understanding or 'risk?perception*' or motivation or 'perceived?need' or 'perceived?necessity' or concern* or 'self?efficacy' or 'health?belief*' or 'causal attributions' or attribution* or attitude* or expectation* or perception* or 'psycho?social' or psychological or depression or personality or mood or anxiety)

and

medication (medic* or treatment or bisphosphonate or strontium?ranelate or alendronic acid, or bisphosphonic acid derivative or raloxifene or risedronic acid)

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APPENDIX 2. Checklist for study inclusion (study 1)¹⁵

Question		Yes (2)	No (1)	Unsure (0)
1 Study design evident and appropriate?				
2 Question / objective sufficiently described?				
3 Method of subject/comparison group selection or source of information/input variables described and appropriate?				
4 Subject (and comparison group, if applicable) characteristics sufficiently described?				
5 Outcome and (if applicable) exposure measure(s) well defined and robust to measurement / misclassification bias? Means of assessment reported?				
6 Sample size appropriate?				
7 Analytic methods described/justified				


¹⁵ Kmet, L., Lee, R., & Cook, L. Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields. 2004. *Alberta: Canada: Alberta Heritage Foundation for Medical Research.*

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Question		Yes (2)	No (1)	Unsure (0)
and appropriate?				
8 Some estimate of variance is reported for the main results?				
9 Results reported in sufficient detail?				
10 Conclusions supported by the results?				

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APPENDIX 3. First page of favourable opinion letter from research ethics committee for Study 2


National Research Ethics Service
South West London REC 3
Room 4W/12 4 Floor West
Charing Cross Hospital
Fulham Palace Road
London W6 8RF
Telephone: 020 3311 7227
Facsimile: 020 3311 7280

Miss Sarah Jane Besser
PhD Student
King's Patient Safety and Service Quality Research Centre
King's College London, 138-142
Strand,
London
WC2R 1HH

03 August 2010

Dear Miss Besser

Study Title: Imagery, illness perceptions and risk perceptions in osteoporosis patients: an exploratory study
REC reference: 10/H0803/101
Protocol number:

The Proportionate Review Sub-committee of the South West London REC 3 Research Ethics Committee reviewed the above application at the meeting held on 28 July 2010.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

APPENDIX 4. Paper published in peer reviewed medical journal (study 2)

Arch Osteoporos (2012) 7:115–124
DOI 10.1007/s11657-012-0089-9

ORIGINAL ARTICLE

How do osteoporosis patients perceive their illness and treatment? Implications for clinical practice

Sarah Jane Besser · Janet E. Anderson · John Weinman

Received: 12 April 2012 / Accepted: 18 June 2012 / Published online: 10 July 2012
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Abstract

Summary Non-adherence inhibits successful treatment of osteoporosis. This study used a theoretical framework to explore osteoporosis patients' cognitive and emotional representations of their illness and medication, using both interviews and drawing. We recorded some misconceptions patients have about their condition and medication which could act as barriers to treatment adherence.

Purpose Despite the high efficacy of current treatments in reducing fracture risk, poor adherence is still a problem in osteoporosis. This qualitative study aims to inform the development of a psychological intervention to increase adherence through the investigation of osteoporosis patients' perceptions of their illness and medication. The self-regulation model (Leventhal) provided the framework for the study.

Method Participants were 14 female outpatients from a London teaching hospital who suffer with osteoporosis or osteopenia. Data were collected using both semi-structured interviews and drawings. Drawings were used to elicit

participants' visual representations (imagery) of their condition.

Results We found that patients held illness and medication beliefs that were not in accord with current scientific evidence. Interviews revealed that participants had good knowledge of what osteoporosis is, but they had low understanding of the role of medication in reducing fracture risk, various concerns about the side effects of medication, poor understanding of the causes of osteoporosis and uncertainty about how it can be controlled. Additionally, drawings elicited more information about the perceived effects of osteoporosis and emotional reactions to the condition.

Conclusions Osteoporosis sufferers need a better understanding of their fracture risk and what they can do to control their condition. Concerns about medication need to be addressed in order to improve adherence, particularly in relation to the management of side effects. Since drawings of osteoporosis were found to arouse emotions, it is concluded that risk communication in osteoporosis could benefit from using visual images.

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King's College London,
2 Basement, 138-142 Strand Bridge House, Strand,

Keywords Adherence · Emotions · Illness perceptions · Medication beliefs · Visual representations

APPENDIX 5. Topic guide (study 2)

Introduction

This is a psychology student project. This interview is in 2 parts. The first is about your thoughts and beliefs about your illness, the second is about medication.

Doctors are becoming increasingly aware of the need to understand patients' views and experiences of their illnesses and conditions. Therefore this study aims to find out about your views and experiences of your osteoporosis and about how you see your bone problem. To do this, I would like to have a conversation with you, in which I will ask you some questions about your illness experience. **It is not a test! There are no right or wrong answers** to the questions I will ask you, this study is being done in order to learn about your experience of your condition. It may sound like some the questions are repetitive. Everything you tell me will be completely confidential. Try and forget that the tape recorder is there is you can.

Carry out demographic questionnaire

Beliefs about illness Questions (Identity and Cause)

In your own words, can you tell me about your bone problem?

Prompts

What is osteoporosis?

What are the symptoms?

Can you describe what you think is happening to your bones? – How does this affect you?

What do you think causes osteoporosis in general? Why do you think it happened to you?

Have you ever suffered a fracture?

What do you think caused your fracture?

Is there anything else you can you tell me about your bone problem?

Drawing Exercise

Now that you have told me a bit about osteoporosis, I would like to move on to the drawing exercise.

Could you draw a picture of 2 bones, 1 with osteoporosis 1 without?

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Could you draw (using stick people drawings for ease) a person with and person without osteoporosis?

Risk Perceptions

Do you think osteoporosis is a serious condition in general?

Prompts

How serious is your own osteoporosis?

Do you think it is serious in comparison to other illnesses, such as cancer, or heart disease?

In your opinion, what is the **worst** that could happen as a result of osteoporosis?

Consequences (Perceived Severity)

What are the consequences of the illness for you?

Prompts

How does your bone problem affect your daily life?

What do you think will happen to you if your bone problem gets worse?

What has your condition stopped you from doing?

Risk Perceptions and Perceived Susceptibility

What is your chance of having a fracture in the next year, compared to other men/women of your age?

Prompt

Is your chance greater or less compared to other men/women of your age?

What are the chances of you having another fracture in your lifetime?

What can you do to reduce your risk of future fracture?

Do you think you will break a bone again? Why? Why not?

Timeline and Cure

How long do you expect to have this condition for?

Prompt

Will you have it for the rest of your life?

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Is there any cure for your condition?

Controllability (Perceived preventability)

Do you think you can stop your bone problem from getting worse? How?

Prompts

How much do you think your treatment can make a difference to your bone problem.

Is there anything else you can do to prevent your condition from getting worse?

Emotions and Coping

Does your bone problem have an effect on your feelings/emotions?

If the patient describes feelings ask, *what do you do to cope with that?*

Can you tell me about when you were diagnosed with your bone problem? (Reserve Question)

Health Behaviour Questions

Now we are going to move on to talk about actions you take to take control of your bone problem (Reserve question).

On a day to day basis, what do you do to manage your bone problem?

Prompts

Have you changed your diet?

Have you altered your exercise uptake?

Medication

Do you do anything to prevent yourself from falling?

Which of these measures do you take? Which do you not take? Why?

Prompt

What stops you from taking protective measures against your bone problem?

Medication Questions (treatment)

Now we are going to move on to talk about your treatment for your bone problem. While we have discussed it before, I am now particularly interested in finding out about problems patients have with sticking to medication regimens.

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What do you think about medication in general? Is it positive or negative? Do you have any concerns about taking medication in general.

What is the treatment for your bone problem? Can you talk me through your medication regime (including how you remember to take it)?

Prompts

What were you told to do with the medication? Were you given any special instructions?

Do you understand why you need to take this medication?

What do you think the medication does?

What are the difficulties with taking your specific osteoporosis medication? What are your concerns about taking it?

Is the medication anything to do with fractures?

Can the medication reduce your risk of fractures?

Prompts

Did you understand how to take your medication? E.g. on an empty stomach?

Do you always take the medication as prescribed?

Have you ever missed a dose of your medication? Why?

Have you ever deliberately missed a dose?

When you were given the prescription, did you feel able to follow it?

What stops you from taking the medication as prescribed?

Efficacy

How much do you feel that the medication has helped your illness?

Prompts

Do you think that the medication will make your bone condition better? Why or why not?

Do you think that medication can help to make your bones strong?

Do you think you need to be on the medication that you were prescribed?

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Do you think that if you take your medication you will have less chance of breaking a bone?

Are there any side effects from your medication? Do these affect whether you decide to take it.

Motivation

Is it important to you to take your medication as prescribed? Why? Why not?

Other information

We know that many patients have difficulties with taking their osteoporosis medication. What do you think could be done by doctors to help other patients to take their medication?

Is there anything else you would like to tell me about your experience of this bone problem before we finish the interview? Anything about the way you think or feel about this illness?

APPENDIX 6. Reliability of the coding framework

This document outlines the thematic framework used to describe the data from the study 'How do osteoporosis patients perceive their illness and treatment? Implications for treatment adherence.' The framework is divided into themes at 3 levels, global themes, themes and sub-themes.

To check that my coding framework is accurate, please use this document to code the data from the transcript you have been given into the 11 global themes. Please make note of any other themes that arise.

Description of global themes

1. Identity

Any mention of symptoms, knowledge of condition, including osteoporosis is a disease in which bones become thin, weak, easy to break, decreased bone mineral density etc.

e.g. "I know they say osteoporosis is painless, I can't really believe that." (participant 14)

2. Cause

Ideas of what caused osteoporosis. Also code if unsure about cause.

Suggestions of the causes of fractures. Also code if unsure about the cause of fracture.

e.g. "I think anyone who would have fallen like that would have fractured. It was a hard fall. I am not able to see all that well so I think this is why I fell over." (Participant 2)

3. Timeline

Discussion of how long the participant expects to have the illness for. Also include any mention of the timeline of the medication

e.g. "You don't get rid of it, do you?" (Participant 12)

4. Controllability/Cure

Any mention whether the illness is controllable/ uncontrollable, or they are unsure of whether it can be controlled. Methods of control include: medication, diet, exercise, vitamin supplementation, falls/fracture prevention (e.g. being careful not to fall over).

Also include any discussion about whether there is a cure for osteoporosis.

e.g. "I'm always conscious that I must be careful, that's the thing I live with." (Participant 9)

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Then you, you never can stop falling over, accidents are going to happen aren't they you know. (Participant 9)

5 Consequences

Physical consequences, impact of activity, or medication as the only consequence. Also include where participants have stated that it does not impact their daily lives.

"It doesn't really, apart from it does mean that I have to take pain medication every day. I can't go through a day without pain medication, you know I've been on the whole range." (Participant 3)

6 Emotions

Any mention words describing emotions or lack of emotions.

e.g. "So if I fractured my spine, I could end up in a wheelchair couldn't I? Which is my biggest fear" (Participant 4)

7 Risk Perceptions

Include mentions of severity of the condition

Participants' responses to the questions (1) What are your chances of having a fracture in the next year, compared to other men and women of your age. (2) What are your chances of having a fracture in your lifetime compared to other men and women of your age?

e.g. "It's the same, well I mean you never know who is going to be hit by a bus, this would cause anyone to fracture, so I'm not at more risk." (Participant 1)

8 Medication beliefs

Discussion of whether medication in general is positive or negative. Discussion of concerns about medication in general and concerns about osteoporosis medication.

"Doctors are enthusiastic to give medicines because that's what they do. I am keen to kind of make sure that it's what I really need, so I'm kind of negative really"
(Participant 13)

9 Adherence

Self-reported adherence to treatment. Includes both intentional and unintentional reasons for non-adherence. Any mention of alterations patients make to their medication prescription.

"Let's say I took it for 6 years, I might have missed it 3 times" (Participant 8)

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10 Relationships




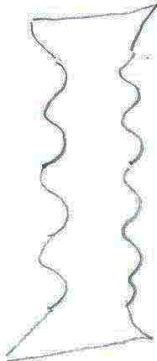
Doctor-patient relationship, social support and feedback

11 Recommendations for future interventions

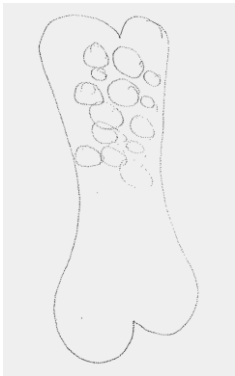
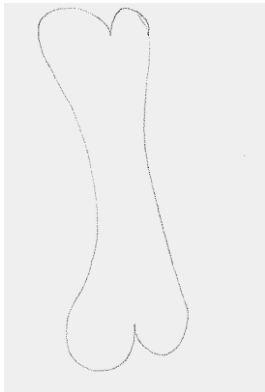
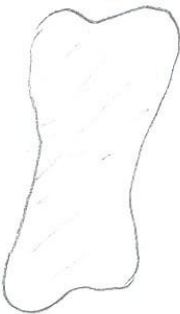
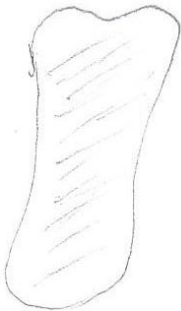
Any ideas participants have given about what could improve adherence for patients who have difficulties with it.

“I also think that showing patients pictures of bones could be useful in helping them to understand what is going on” (Participant 1)


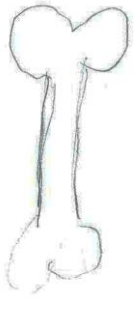
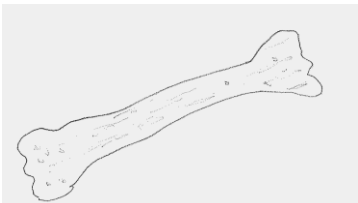

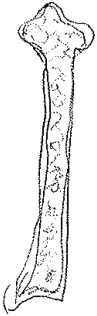
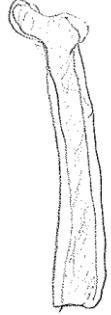
APPENDIX 7. Patient drawings of bones with and without osteoporosis (study 2)

Participant number	Bone with osteoporosis	Bone without osteoporosis
1		
2		


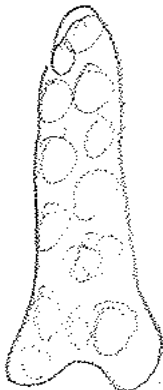
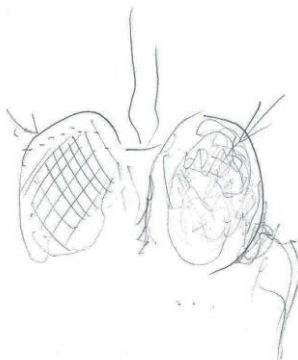
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Participant number	Bone with osteoporosis	Bone without osteoporosis
3		
4		

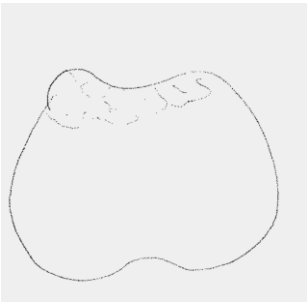





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Participant number	Bone with osteoporosis	Bone without osteoporosis
5		
6		
7		





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Participant number	Bone with osteoporosis	Bone without osteoporosis
8		
9		





The psychological factors in adherence to osteoporosis medication: an intervention development study

Participant number	Bone with osteoporosis	Bone without osteoporosis
10		
11		
12		





The psychological factors in adherence to osteoporosis medication: an intervention development study

Participant number	Bone with osteoporosis	Bone without osteoporosis
13		
14		

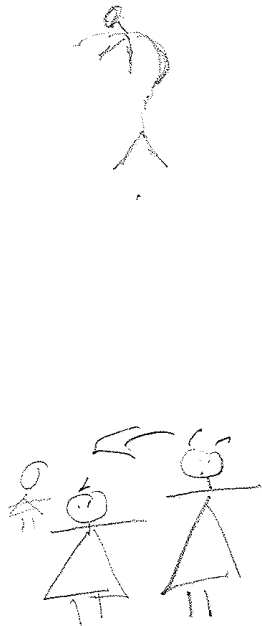



APPENDIX 8. Participant drawings of people with and without osteoporosis

Participant Number	Person with osteoporosis	Person without osteoporosis
8		
9		



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Participant Number	Person with osteoporosis	Person without osteoporosis
10		
11		

The psychological factors in adherence to osteoporosis medication: an intervention development study

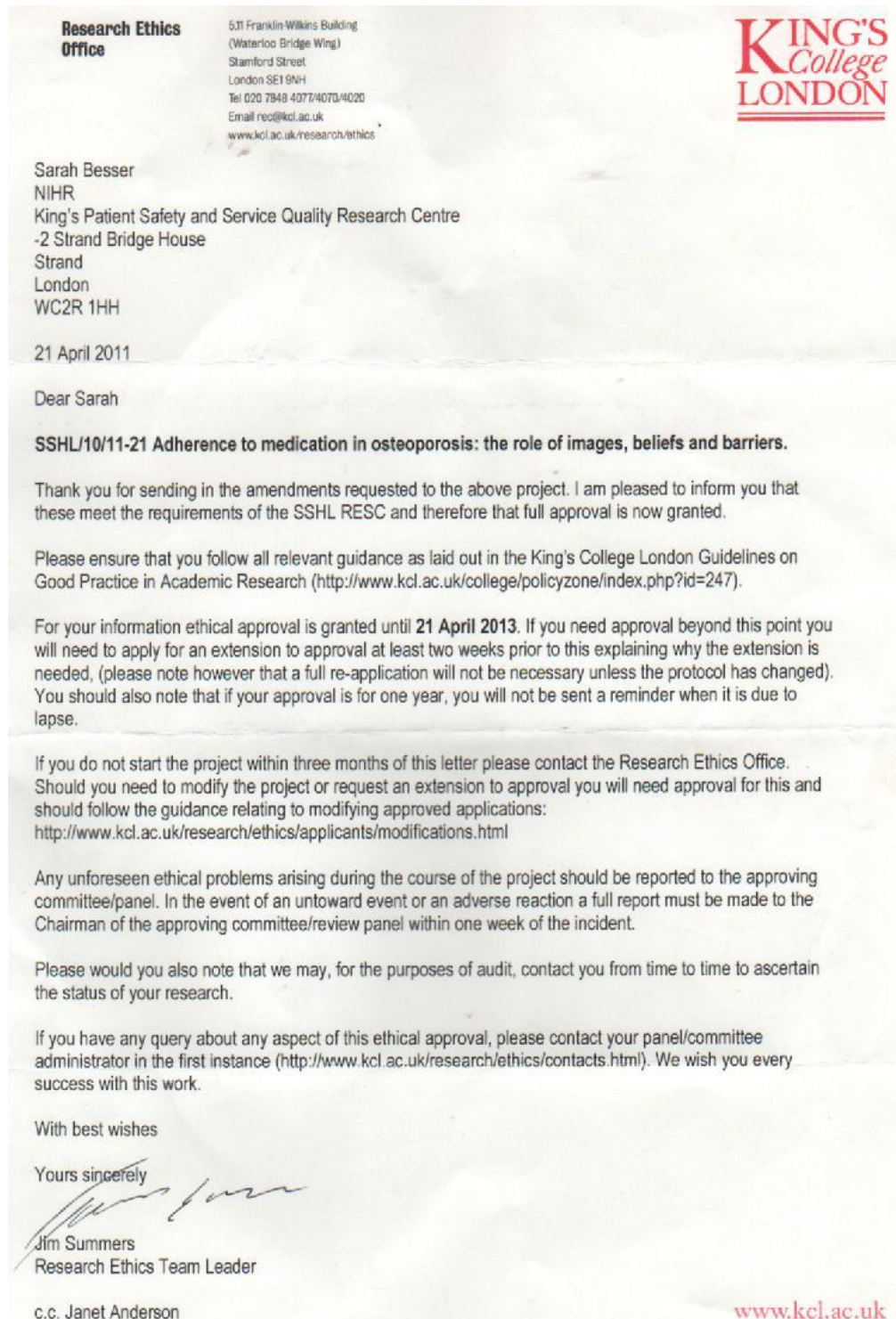
Participant Number	Person with osteoporosis	Person without osteoporosis
12	 <p>The sketches in this cell depict a person with a hunched back, suggesting osteoporosis, and a family consisting of a man, a woman, and a small child.</p>	 <p>The sketch in this cell depicts a person with a normal upright posture, representing someone without osteoporosis.</p>
13	 <p>The sketches in this cell depict a person with a hunched back, suggesting osteoporosis, and a family consisting of a man, a woman, and a small child.</p>	 <p>The sketch in this cell depicts a person with a normal upright posture, representing someone without osteoporosis.</p>

The psychological factors in adherence to osteoporosis medication: an intervention development study

Participant Number	Person with osteoporosis	Person without osteoporosis
14		

The psychological factors in adherence to osteoporosis medication: an intervention development study

APPENDIX 9. First page of favourable opinion letter from research ethics committee for Study 2



APPENDIX 10. Contextual data collection questionnaire (study 3)

1. How many osteoporosis clinics do you run each week?
2. How many patients are seen at each clinic (approximately)?
3. How often are patients usually followed up? e.g. yearly
4. How many times do you usually see patients before discharge?
5. What is the allotted duration for each patient's consultation?
6. Do you currently offer any adherence to medication interventions to patients? e.g. written materials, education etc.
7. Is there anything else you would like to note about your clinic which may be relevant to research investigating adherence to medication?

APPENDIX 11. Demographic data collection sheet (study 3)

Name	
Age	
Ethnicity e.g. British, Irish, Asian etc.	
Occupation or previous occupation	
Does anyone in your family have osteoporosis?	
Total Number of Fractures	
Number of years with Osteoporosis	
How many people do you live with?	
Are you are smoker?	
Are you on medication for osteoporosis?	
Name of osteoporosis medication	
Have you ever had a bone scan?	
Telephone Number	

Please read below and tick as appropriate:

- I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the data protection act 1998. ☐
- I agree to be invited for a future study (there is no obligation to take part in future studies) ☐
- I would like to receive a report of the findings from this study (and for my contact details to be stored for this ☐

Home address or email address	
-------------------------------	--

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Please list all other medical conditions you have (if any)	Please list all the medications you are prescribed

APPENDIX 12. Illness Perceptions Questionnaire Revised (IPQ-R) adapted for osteoporosis (study 3):

Your osteoporosis

We are interested in your views about your osteoporosis
These are statements other people have made about their
osteoporosis

Please show how much you agree or disagree with each of the
following statements by ticking one of the boxes

Views about your osteoporosis	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
1) Having this osteoporosis makes me feel anxious					
2) I expect to have this osteoporosis for the rest of my life					
3) I get depressed when I think about my osteoporosis					
4) I go through cycles in which my osteoporosis gets better and worse					
5) My osteoporosis causes difficulties to those who are close to me					
6) My osteoporosis has serious financial consequences for me					
7) I have the power to influence my osteoporosis					
8) My osteoporosis is a serious condition					
9) The course of my osteoporosis depends on me					

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Views about your osteoporosis	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
10) My osteoporosis is likely to be permanent rather than temporary					
11) My osteoporosis is very unpredictable					
12) My osteoporosis makes me feel afraid					
13) My osteoporosis makes me feel angry					
14) My osteoporosis strongly affects the way others see me					
15) My osteoporosis will improve in time					
16) My osteoporosis has major consequences on my life					
17) What I do can determine whether my osteoporosis gets better or worse					
18) My osteoporosis will last for a long time					
19) My treatment can control my osteoporosis					
20) My treatment will be effective in curing my osteoporosis					
21) When I think about my osteoporosis I get upset					

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Views about your osteoporosis	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
22) I have a clear picture or understanding of my osteoporosis					
23) The negative effects of my osteoporosis can be prevented (avoided) by my treatment					
24) My osteoporosis does not worry me					
25) The symptoms of my osteoporosis change a great deal from day to day					
26) My osteoporosis doesn't make any sense to me					
27) I don't understand my osteoporosis					
28) My osteoporosis is a mystery to me					
29) The symptoms of osteoporosis are puzzling to me					
30) There is nothing which can help my osteoporosis					
31) There is very little that can be done to cure my osteoporosis					
32) Nothing I do will affect my osteoporosis					
33) My actions will have no effect on the outcome of my osteoporosis					
34) My osteoporosis does not have much effect on my life					

Your views about symptoms you have experienced

We would like to ask you about any symptoms you may have experienced since finding out about your osteoporosis.

Some people do experience symptoms related to osteoporosis whilst others don't

Similarly, some people experience symptoms that are related to their medication and others don't

In the table below is a list of common symptoms

Please show whether you have experienced each of the following symptoms recently by circling Yes or No

For each symptom that you have experienced recently, please then show whether you believe it is related to your OSTEOPOROSIS or to the MEDICINE you take for your osteoporosis

If you don't know whether the symptom is related to your osteoporosis, or the medication you take for your osteoporosis, please circle don't know.

Symptom	I have experienced this symptom recently		If answer is yes	This symptom is related to my osteoporosis			This symptom is related to the medicine I take for my osteoporosis		
35) Pain	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
36) Sore Throat	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
37) Nausea	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know

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Symptom	I have experienced this symptom recently		If answer is yes	This symptom is related to my osteoporosis			This symptom is related to the medicine I take for my osteoporosis		
38) Breathlessness	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
39) Weight Loss	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
40) Fatigue	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
41) Stiff joints	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
42) Sore Eyes	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
43) Wheeziness	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
44) Headaches	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know
45) Upset Stomach	Yes	No	If answer is yes	→Yes	No	Don't know	→Yes	No	Don't know

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Symptom	I have experienced this symptom recently		If answer is yes	This symptom is related to my osteoporosis			This symptom is related to the medicine I take for my osteoporosis		
46) Sleep Difficulties	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
47) Dizziness	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
48) Loss of strength	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
49) Loss of libido	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
50) joint pain	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
51) Feeling flushed	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
52) Fast heart rate	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know
53) Pins and needles	Yes	No	If answer is yes →	Yes	No	Don't know →	Yes	No	Don't know

Please turn to next Page

Your views about symptoms you may have experienced

(continued)

If you have experienced any other symptoms recently (not mentioned in the table above) that you believe may have been related to your osteoporosis, please write them in the table below

Please show whether you believe they are related to your osteoporosis or to the medicine you take for your osteoporosis by circling yes, no or don't know.

Symptom	I have experienced this symptom recently		This symptom is related to my osteoporosis			This symptom is related to the medicine I take for my osteoporosis		
54)	Yes	No	Yes	No	Don't know	Yes	No	Don't know
	Yes	No	Yes	No	Don't know	Yes	No	Don't know
	Yes	No	Yes	No	Don't know	Yes	No	Don't know

Please turn to next page

Symptoms

If you have experienced symptoms that you think are related to your osteoporosis, please answer the following questions. If not, please go on to the next page

We are interested in your views about your symptoms related to your osteoporosis

These are statements other people have made about their symptoms
Please show how much you agree or disagree with them by ticking one of the boxes

Your views about your osteoporosis symptoms	Strongly disagree	Disagree	Don't know	Agree	Strongly agree
55) There is a lot I can do to control my symptoms					
56) My symptoms come and go in cycles					
57) The symptoms of my osteoporosis change a great deal from day to day					

Your views about causes of osteoporosis

We are interested in your own views about what caused your osteoporosis

Below is a list of possible causes

Please show how much you agree and disagree that they were causes FOR YOU by ticking one of the boxes for each possible cause

As people are very different, there are no correct answers for these questions

Your views on possible causes of your osteoporosis	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
58) Stress or Worry					
59) Heredity – it runs in my family					
60) A germ or virus					
61) Diet or eating habits					
62) Chance or bad luck					
63) Poor medical care in my past					
64) Pollution in the environment					

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Your views on possible causes of your osteoporosis	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
65) My own behaviour					
66) My mental attitude e.g. thinking about life negatively					
67) Family problems or worries					
68) Overwork					
69) My emotional state e.g. feeling down, lonely, anxious, empty					
70) Ageing					
71) Alcohol					
72) Smoking					
73) Accident or injury					
74) My personality					
75) Poor immune System					

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In the table below, please list the three most important factors that you believe caused YOUR osteoporosis

You may use any of the items from the box above, or you may have additional ideas of your own.

If you can't think of three things that caused your osteoporosis, just write one or two.

	The most important causes of my osteoporosis
Cause 1	
Cause 2	
Cause 3	

End of questionnaire

APPENDIX 13. The beliefs about medication questionnaire, adapted for osteoporosis (study 3)

**YOUR VIEWS ABOUT
YOUR OSTEOPOROSIS MEDICINE**

We would like to ask you about your personal views about medicines prescribed for you

These are statements other people have made about their medicines

Please show how much you agree or disagree with them by ticking the appropriate box.

	Views about your osteoporosis medicine	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
BS1	My health at present depends on my osteoporosis medicine					
BS2	Having to take my osteoporosis medicine worries me					
BS3	My life would be impossible without my osteoporosis medicine					
BS5	I sometimes worry about long-term effects of my osteoporosis medicine					
BS4	Without my osteoporosis medicine I would be very ill					
BS6	My osteoporosis medicine is a mystery to me					
BS7	My health in the future will depend on my osteoporosis medicine					
BS8	My osteoporosis medicine disrupts my life					
BS9	I sometimes worry about becoming too dependent on my osteoporosis medicine					
BS10	My osteoporosis medicine protects me from becoming worse					

End of questionnaire

APPENDIX 14. The Medication Adherence Report Scale (MARS) (studies 3 and 5)

QUESTIONS ABOUT USING YOUR OSTEOPOROSIS MEDICINES

Many people find a way of using their medicines which suits them.
This may differ from the instructions on the label or from what their
doctor has said.

We would like to ask you 6 questions about how you use your medicines

Here are some ways in which people have said that they use their
medicines

For each of the statements, please tick the box which best applies to
you

		Always	Often	Sometimes	Rarely	Never
MARS1	I forget to take my medicines					
MARS2 1	I alter the dose of my medicines					
MARS3	I stop taking my medicines for a while					
MARS4	I decide to miss out a dose					
MARS5	I take less than instructed					
During the last month, how many doses of your osteoporosis medication have you missed?						

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APPENDIX 15. The Risk Perceptions Questionnaire (RPQ) (studies 3 and 5)

The Risk Perceptions Questionnaire

This questionnaire will ask you about how serious a condition you think osteoporosis is. There are no right or wrong answers, we are interested in your opinion.

Please circle either strongly disagree, disagree, neutral, agree or strongly agree for each question, numbers 1 – 12.

1) I think that OSTEOPOROSIS is a serious disease

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

2) I think OSTEOPOROSIS is a fatal disease.

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

3) It is likely that I am at risk for having a fracture

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

4) I feel that I may get a fracture in the future

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

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5) I am protected against fractures if I use medication as prescribed

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

6) Using medication is an effective way to prevent fractures

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

7) Osteoporosis medication is easy for me to use

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

8) I can use Medication without difficulty

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

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9) I feel frightened of OSTEOPOROSIS

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

10) I feel frightened of having a fracture in the future

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

11) The subject of OSTEOPOROSIS makes me anxious

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

12) I intend to take my osteoporosis medication as prescribed

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

End of Questionnaire

APPENDIX 16. Difficulties Of Taking Osteoporosis Medication Questionnaire (DOTMQ) (studies 3 and 5)

Difficulties with taking osteoporosis medication questionnaire

Please tick yes or no for each statement about your osteoporosis medication

	YES	NO		YES	NO
Interferes with daily activities			Don't like taking medication every week		
Hard to swallow pills/liquid			Don't understand how to take them		
Do not like the taste			Don't want to take them		
Forget			Was not at home		
Not feeling well			Don't like the side effects		
Not necessary			Ran out of medication		
Decided not to			Can't afford		

Do you have any other difficulties?

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APPENDIX 17. Scoring the Illness Perceptions Questionnaire Revised – for osteoporosis (3)

Identity – total the number of yes for each participant

Timeline (acute/chronic) -Items: 2,10,**15**,18

Consequences – Items: 5, 6, 8, 14,16,**34**

Personal Control – Items: 7,9, 17,32,**33**,55

Treatment control –Items: 19,20,23, **30, 31**

Illness coherence – items: 22,26,27,28,29

Timeline (Cyclical) – items: 25,(57), 4, 11,56

Emotional representations - items: 1, 3, 12,13, 21, **24**,

Reverse score: IPQ15, IPQ24, IPQ26, IPQ27, IPQ28, IPQ29, IPQ30, IPQ31, IPQ32, IPQ33 and IPQ34.

Scoring the beliefs about medication questionnaire

Necessity – items: 1,3,5,7,10

Concerns – items: 2,4,6,8,9

Reverse score: All

Scoring the risk perceptions questionnaire

Severity – items: 1,2

Susceptibility – items: 3,4

Response-efficacy – items: 5,6

Self-efficacy – items: 7,8

Emotions – items: 9,10,11

Motivation – item 12

Reverse Score: None

APPENDIX 18. Distribution of extended SRM scores (study 3)

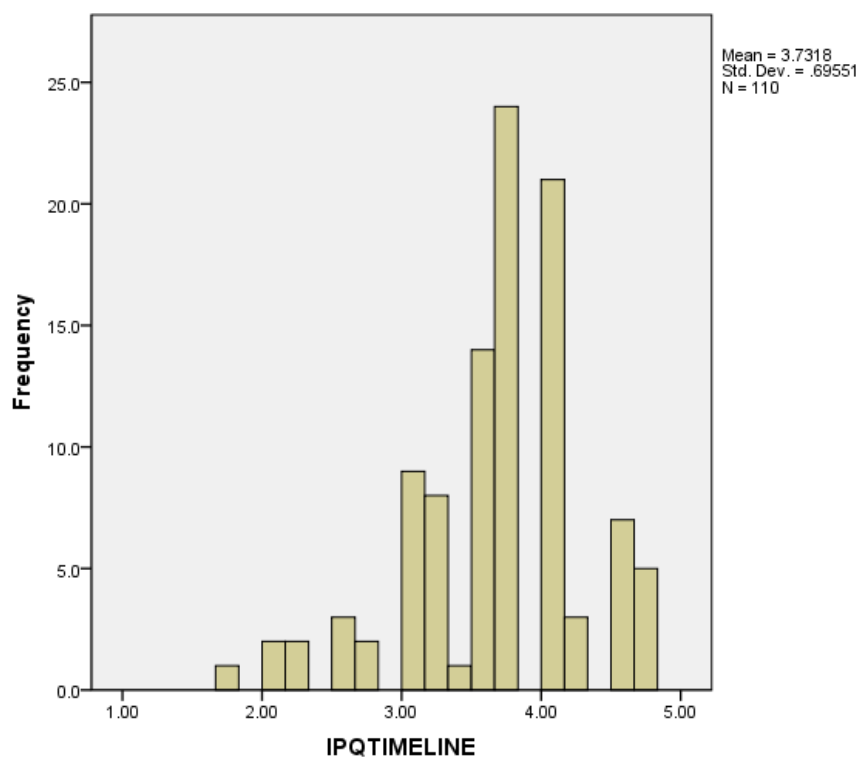


Figure 41. Distribution of IPQ timeline scores

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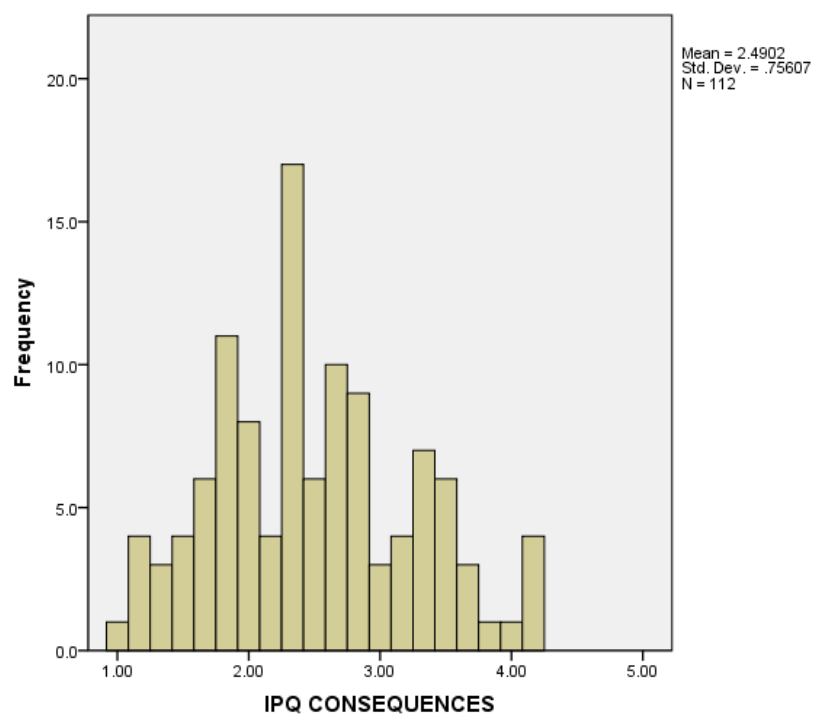


Figure 42. Distribution of IPQ consequences score

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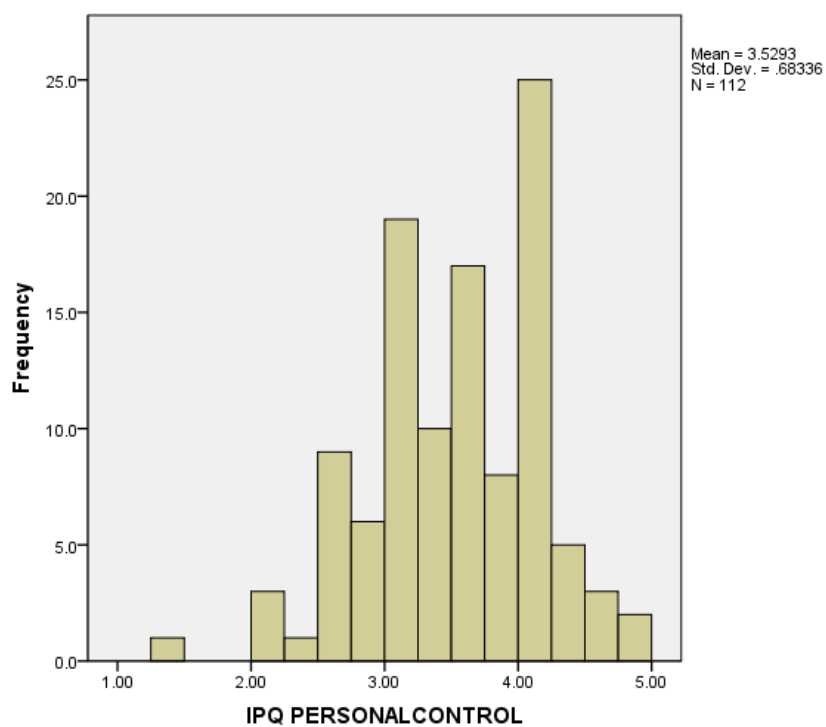


Figure 43. Distribution of IPQ personal control scores

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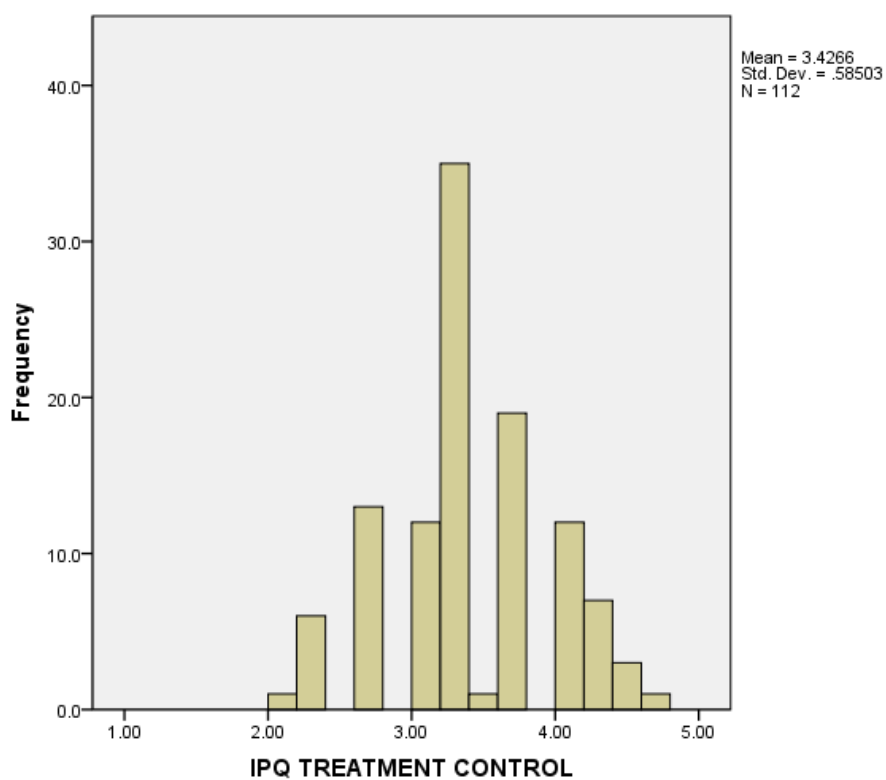


Figure 44. Distribution of IPQ treatment control scores

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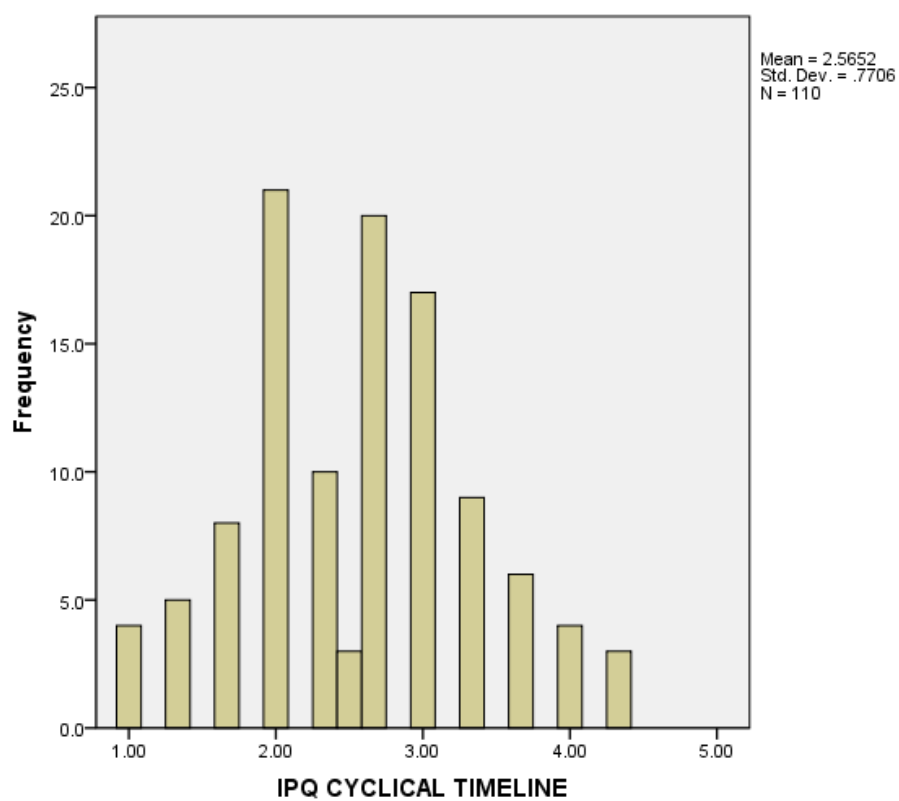


Figure 45. Distribution of IPQ cyclical timeline scores

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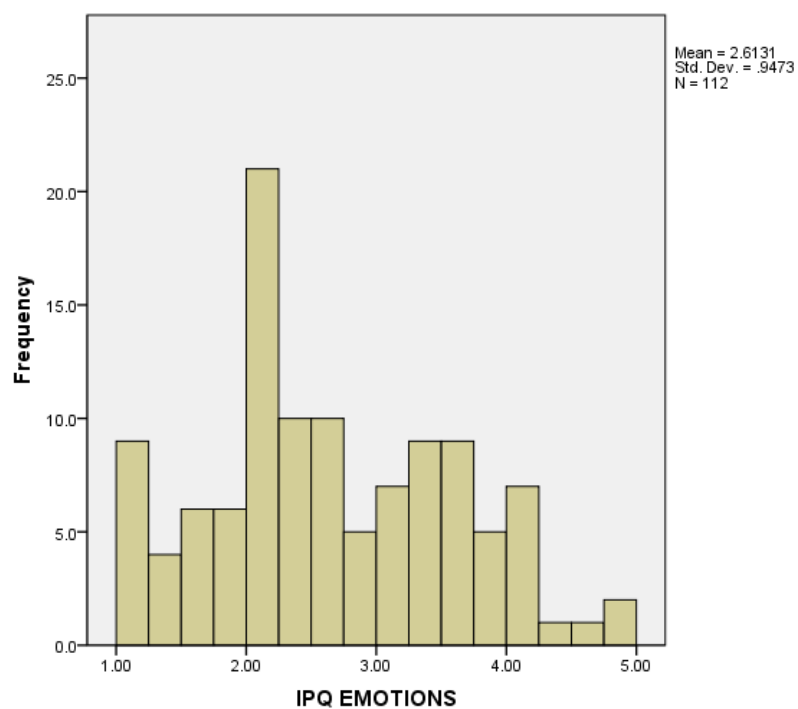


Figure 46. Distribution of IPQ emotions scores

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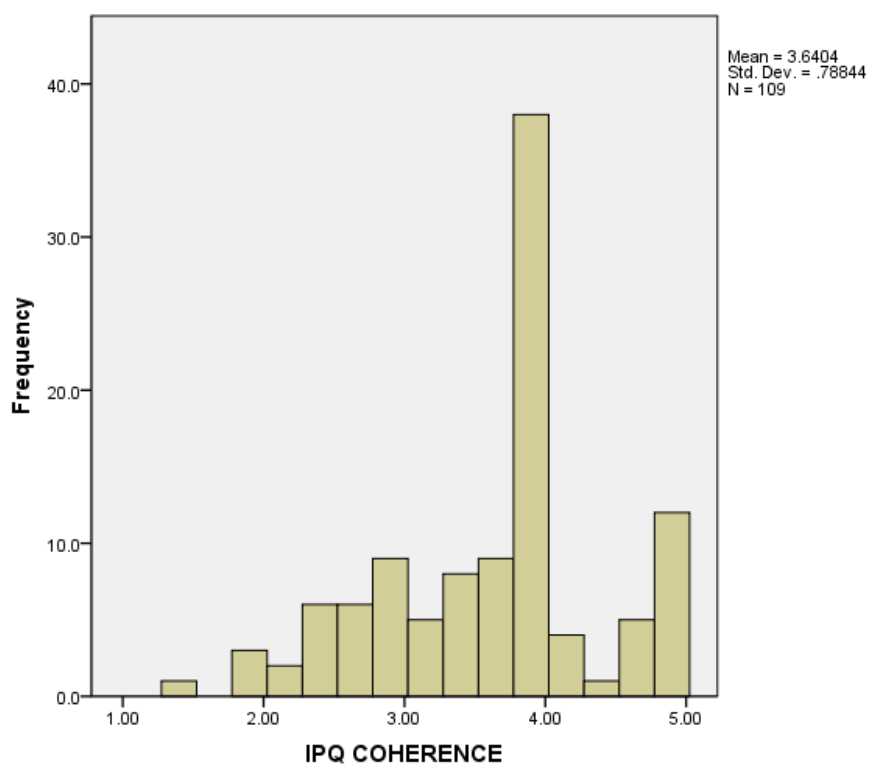


Figure 47. Distribution of IPQ coherence scores

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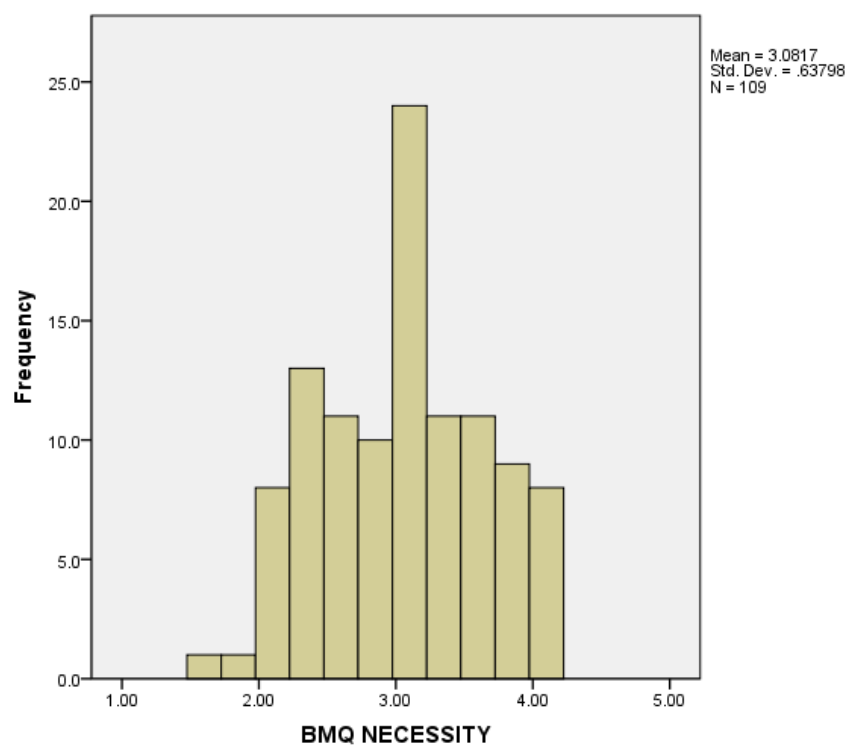


Figure 48. Distribution of BMQ necessity scores

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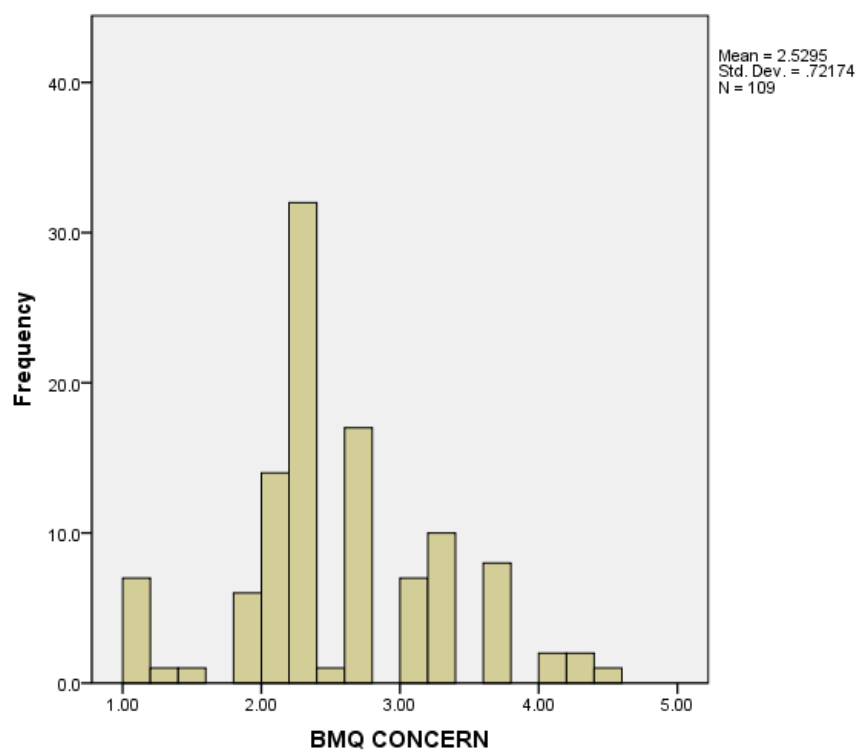


Figure 49. Distribution of BMQ concerns scores

APPENDIX 19. Distribution of RPQ scores (study 3)

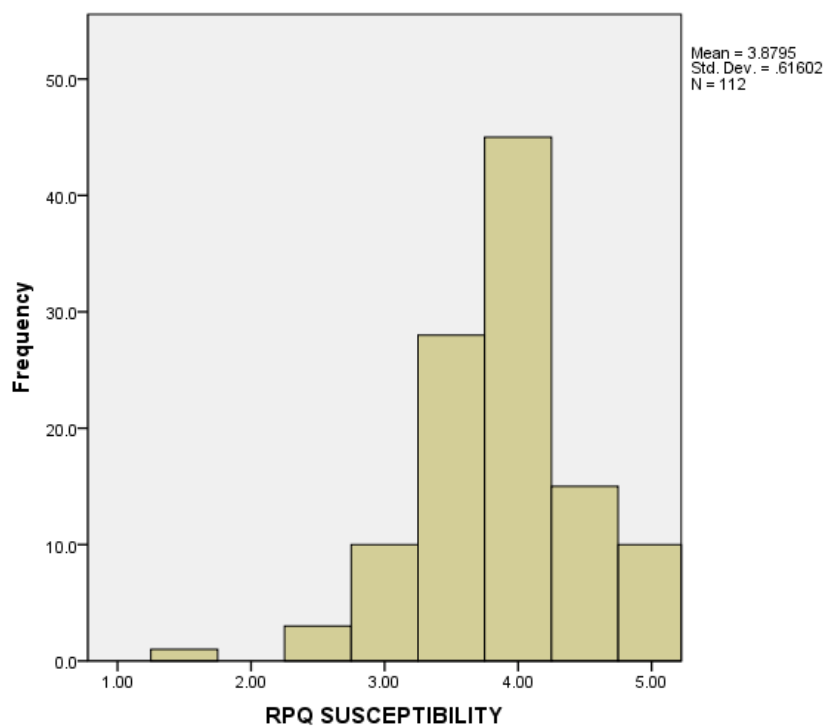


Figure 50. Distribution of RPQ susceptibility scores

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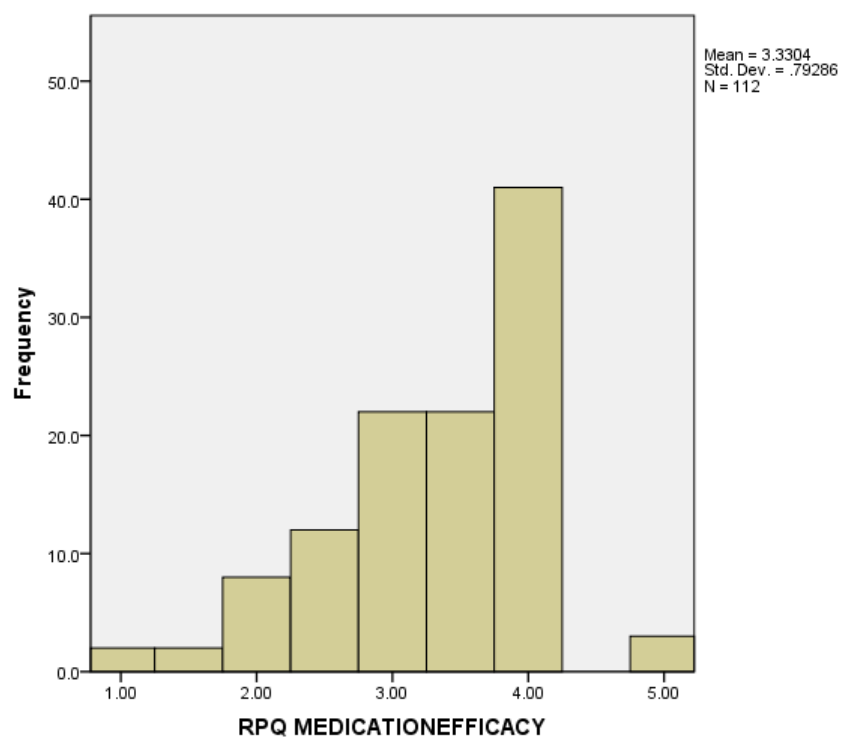


Figure 51. Distribution of RPQ medication efficacy scores

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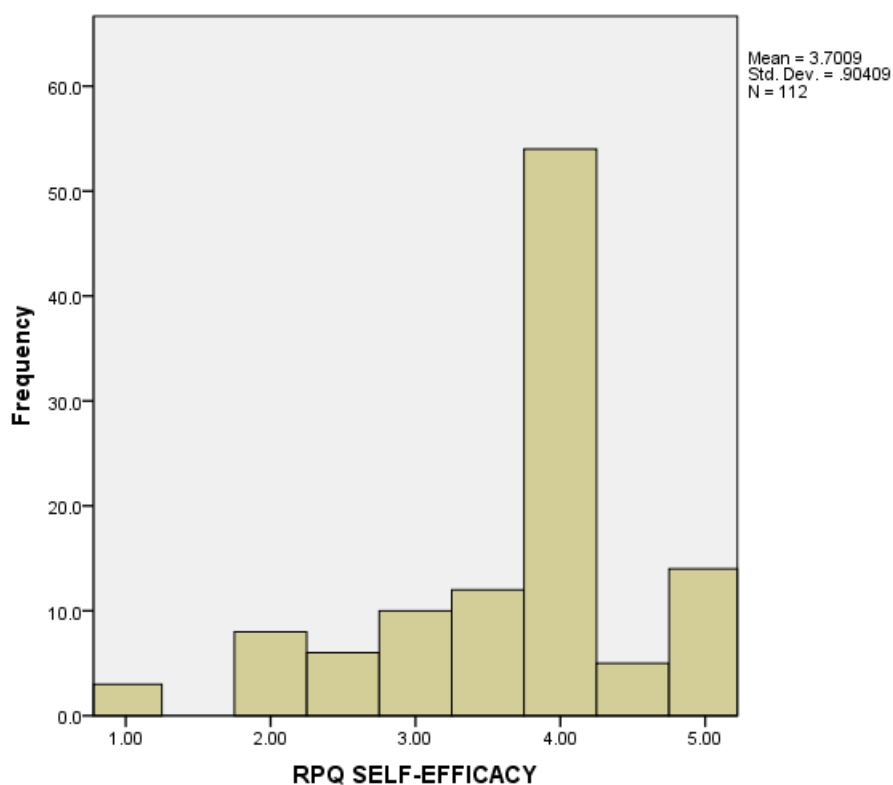


Figure 52. Distribution of self-efficacy scores

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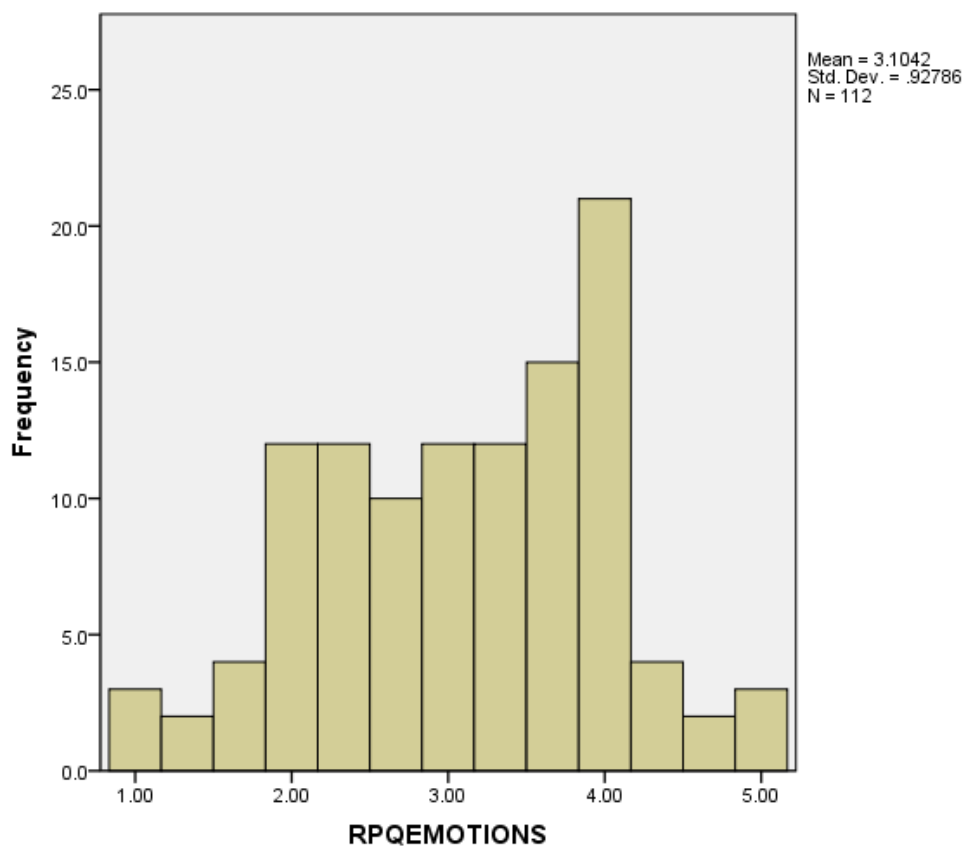


Figure 53. Distribution of RPQ emotion scores

APPENDIX 20. All study scale correlations (study 3)

Scales	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
2	.414**																			
3	.684**	.215																		
4	.386**	.319**	.247*																	
5	.152	.118	.015	.443**																
6	.289**	.340**	.179	.660**	.370**															
7	-.036	.024	-.105	-.049	-.088	-.108														
8	.408**	.447**	.116	.394**	.156	.443**	.129													
9	-.109	-.161	.034	-.217*	.133	-.353**	-.198*	-.187*												
10	-.131	-.164	-.025	-.184	-.066	-.230*	-.485**	-.296**	.565**											
11	-.204	-.254**	-.150	-.176	.081	-.270**	.188	-.172	.376**	.312**										
12	.317**	.373**	.037	.313**	.037	.501**	-.038	.508**	-.106	-.021	-.277**									
13	.350**	.459**	.233*	.474**	.264**	.359**	.084	.755**	-.106	-.234*	-.187	.413**								
14	.223*	.292**	.288*	.418**	.370**	.322**	.033	.363**	-.128	-.121	-.226*	.258**	.562**							
15	.074	.041	-.039	.096	.127	.029	.049	.317**	.116	.104	.160	.111	.282**	.118						
16	.215*	.102	-.065	.019	.182	-.013	.240*	.375**	-.034	-.085	.166	.079	.339**	.014	.367**					
17	-.010	-.138	.133	-.089	-.098	-.107	-.230*	-.088	.339**	.532**	.162	.035	-.110	-.131	.211**	-.185				
18	-.090	-.084	-.281*	-.119	-.208	-.114	.173	.036	-.077	-.156	-.020	-.087	-.064	-.386**	-.018	-.045	-.144			
19	.252*	.320**	.097	.407**	.254**	.284**	.161	.547**	-.148	-.196*	-.157	.282**	.787**	.496**	.302**	.445**	-.027	-.093		
20	-.146	-.233*	-.132	-.185	-.003	-.188	.189	-.178	-.040	.127	.222*	-.161	-.194*	-.314**	.172	.298**	.056	.228*	-.005	

Note; *<.05; **<.001. Key can be found on the next page

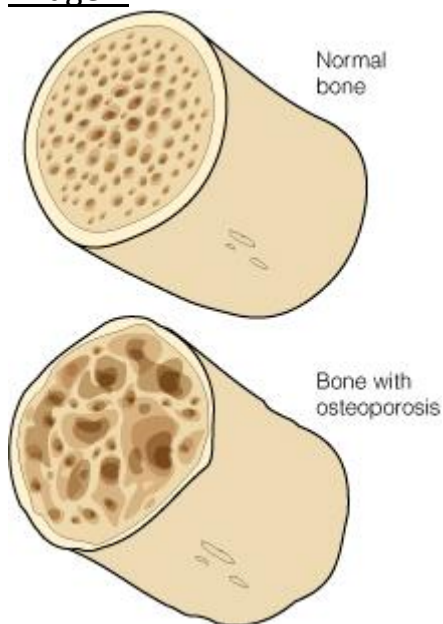
Table 48. Key for APPENDIX 20. All study scale correlations

1.Osteoporosis symptoms	2.General symptoms	3.Medication related symptoms	4.Psychological Attribution	5.Risk Factor Attribution	6.Immune Attribution	7.Timeline (acute)
8. Consequences	10. Personal Control	10. Treatment Control	11. Coherence	13. Timeline (cyclical)	13.Emotions	14.Concerns
15. Necessity	17. Susceptibility	17.Medication efficacy	18.Self-efficacy	19.Emotions	20.Motivation	

APPENDIX 21. Osteoporosis Images Questionnaire (OIQ) (study 4)

After looking at each picture, please tick in the table below how the picture makes you feel, e.g. tick strongly agree if it makes you feel fear and tick strongly disagree if it does not make you feel fear. There are 5 pictures to rate. There are 9 questions which are the same for each image throughout the questionnaire.

Image 1



Your bone can look more like normal bone if you take your medication for osteoporosis

When I look at this picture I feel....

Frightened about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Informed about the effects of osteoporosis medication

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Angry about osteoporosis

Strongly disagree

Disagree

Neutral

Agree

Strongly agree

Motivated to take action to improve my osteoporosis

Strongly disagree

Disagree

Neutral

Agree

Strongly agree

Depressed about my osteoporosis

Strongly disagree

Disagree

Neutral

Agree

Strongly agree

Confident I can take action to improve my osteoporosis

Strongly disagree

Disagree

Neutral

Agree

Strongly agree

Worried about my osteoporosis

Strongly disagree

Disagree

Neutral

Agree

Strongly agree

Confident that medication will improve osteoporosis

Strongly

Disagree

Neutral

Agree

Strongly agree

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disagree

☐☐☐☐☐

There is no point taking action to try and improve osteoporosis

Strongly
disagree

☐

Disagree

☐

Neutral

☐

Agree

☐

Strongly agree

☐

If you have any other comments about how image 1 makes you feel please write in the lines below.

.....

.....

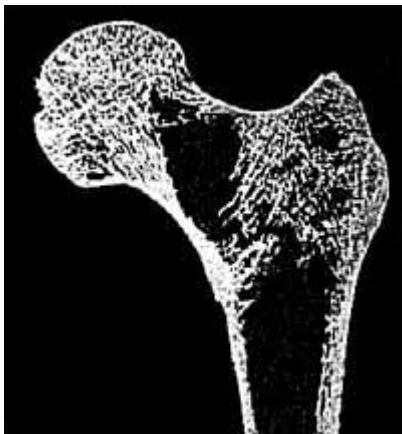
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Image 2

Osteoporotic bone



Normal Bone



Your bone can look more like normal bone if you take your medication for osteoporosis

When I look at this picture I feel....

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Frightened about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Informed about the effects of osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Angry about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Motivated to take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Depressed about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Confident I can take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Worried about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Confident that medication will improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

There is no point taking action to try and improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you have any other comments about how image 2 makes you feel please write in the lines below.

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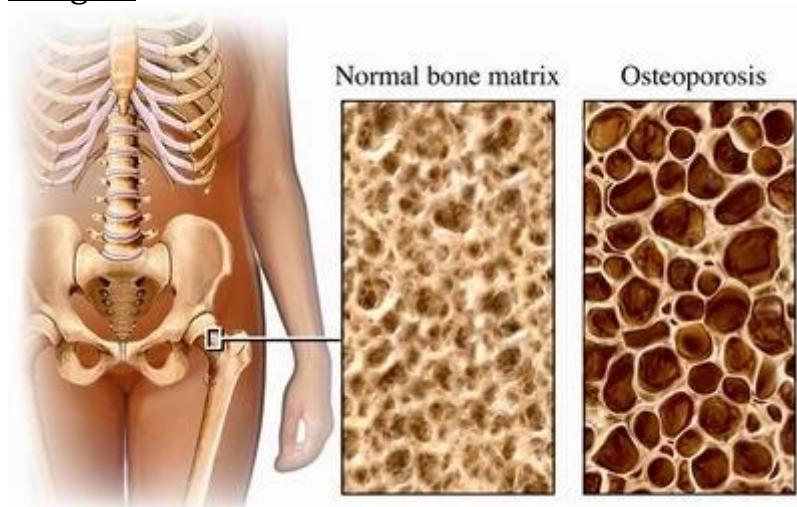
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The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Image 3



Your bone can look more like normal bone if you take your medication for osteoporosis

When I look at this picture I feel....

Frightened about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Informed about the effects of osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Angry about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Motivated to take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Depressed about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Confident I can take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Worried about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Confident that medication will improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

There is no point taking action to try and improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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If you have any other comments about how image 3 makes you feel please write in the lines below.

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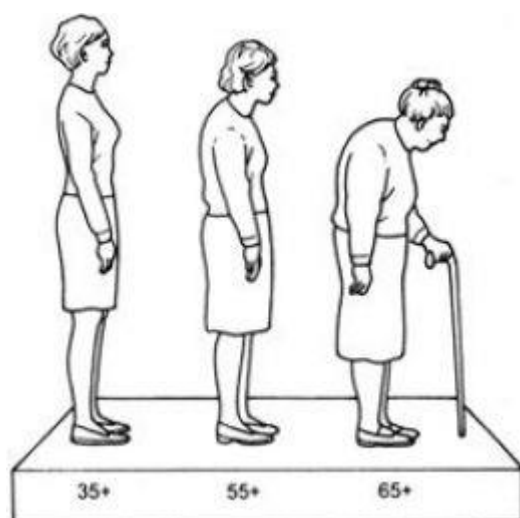
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Image 4



If you take your medication you can stop your osteoporosis from getting worse

When I look at this picture I feel....

Frightened about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Informed about the effects of osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Angry about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Motivated to take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Depressed about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Confident I can take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Worried about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Confident that medication will improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

There is no point taking action to try and improve osteoporosis

Strongly
disagree

☐

Disagree

☐

Neutral

☐

Agree

☐

Strongly agree

☐

If you have any other comments about how image 4 makes you feel please write in the lines below.

.....



.....

.....

.....

.....

Image 5

Osteoporotic Bone	Normal Bone
	

Your bone can look more like normal bone if you take your medication for osteoporosis

When I look at this picture I feel....

Frightened about osteoporosis

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Informed about the effects of osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Angry about osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Motivated to take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Depressed about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Confident I can take action to improve my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Worried about my osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Confident that medication will improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

There is no point taking action to try and improve osteoporosis

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you have any other comments about how image 5 makes you feel please write in the lines below.

.....

.....

.....

.....

.....

End of Questionnaire

This is the final questionnaire, thank you very much for taking the time to take part in this study

Please now return the questionnaires in the stamped addressed envelope provided

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

APPENDIX 22. Scoring the image questionnaire (study 4)

For each image

Positive influence: 2,4,6,8

Negative influence: 1,3,5,7,9

Reverse Score: None

APPENDIX 23. Distributions of image rating scales (study 4)¹⁶

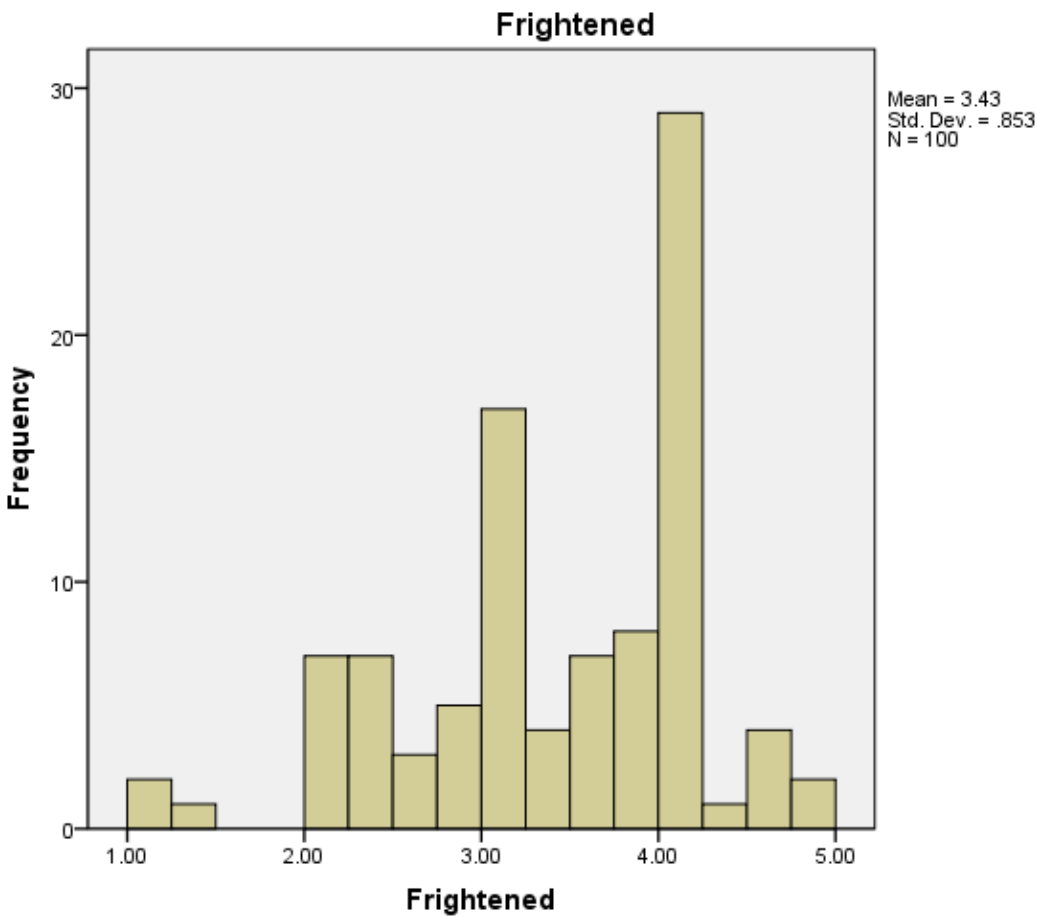


Figure 54. Distribution of frightened rating scores

¹⁶ A high score indicates a high level of response. For example a score of five signifies strong agreement that the image was frightening.

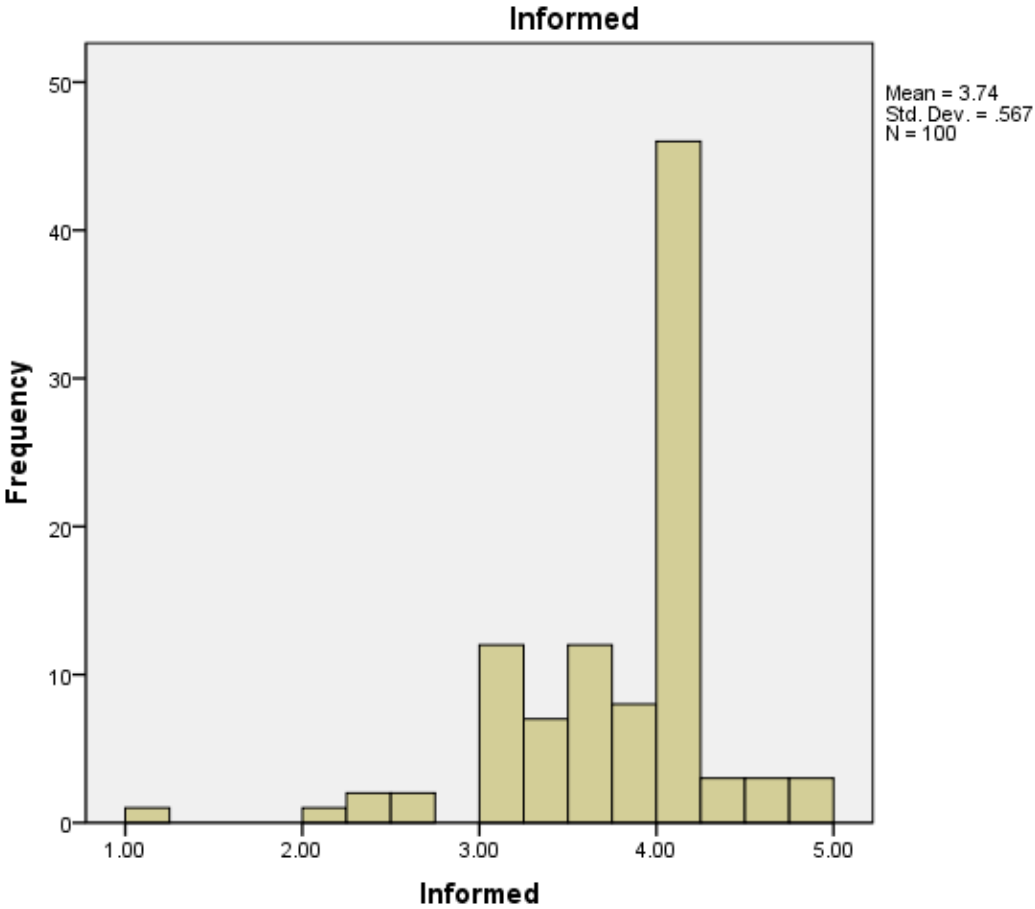


Figure 55. Distribution of informed image rating scores

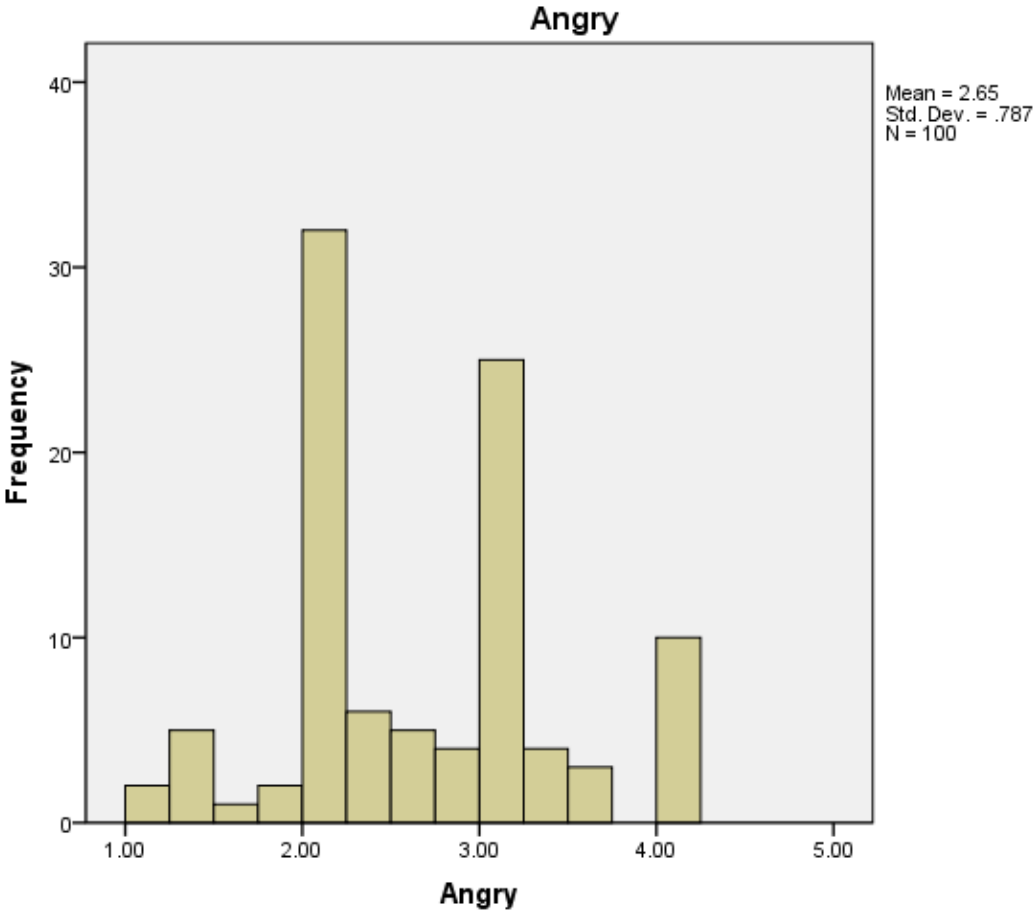


Figure 56. Distribution of angry rating scores

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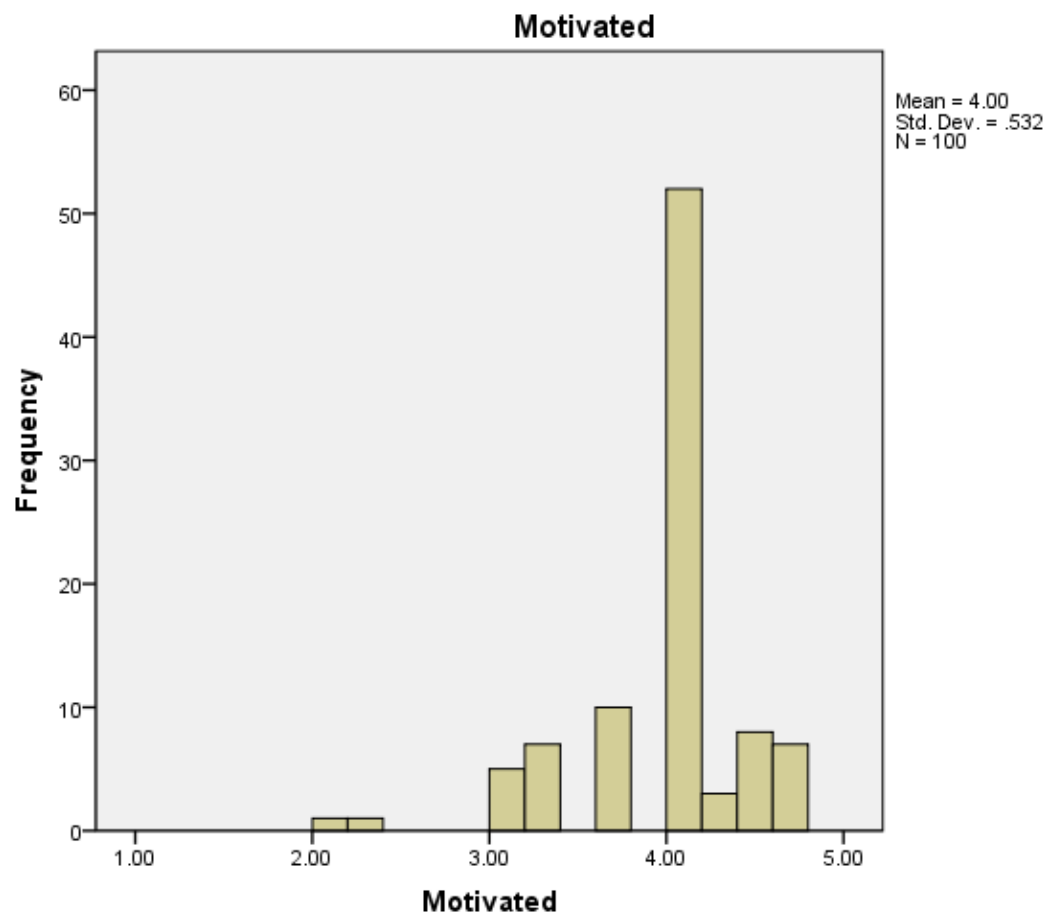


Figure 57. Distribution of motivated rating scores

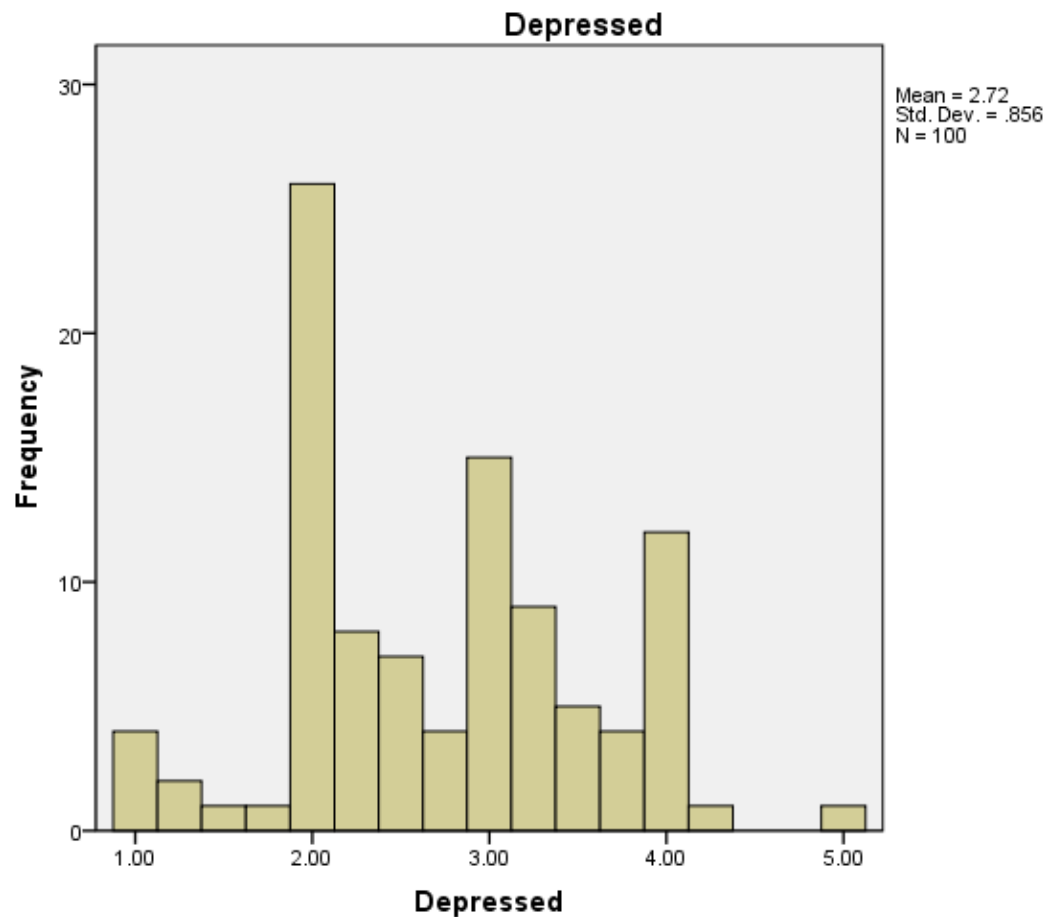


Figure 58. Distribution of depressed rating scores

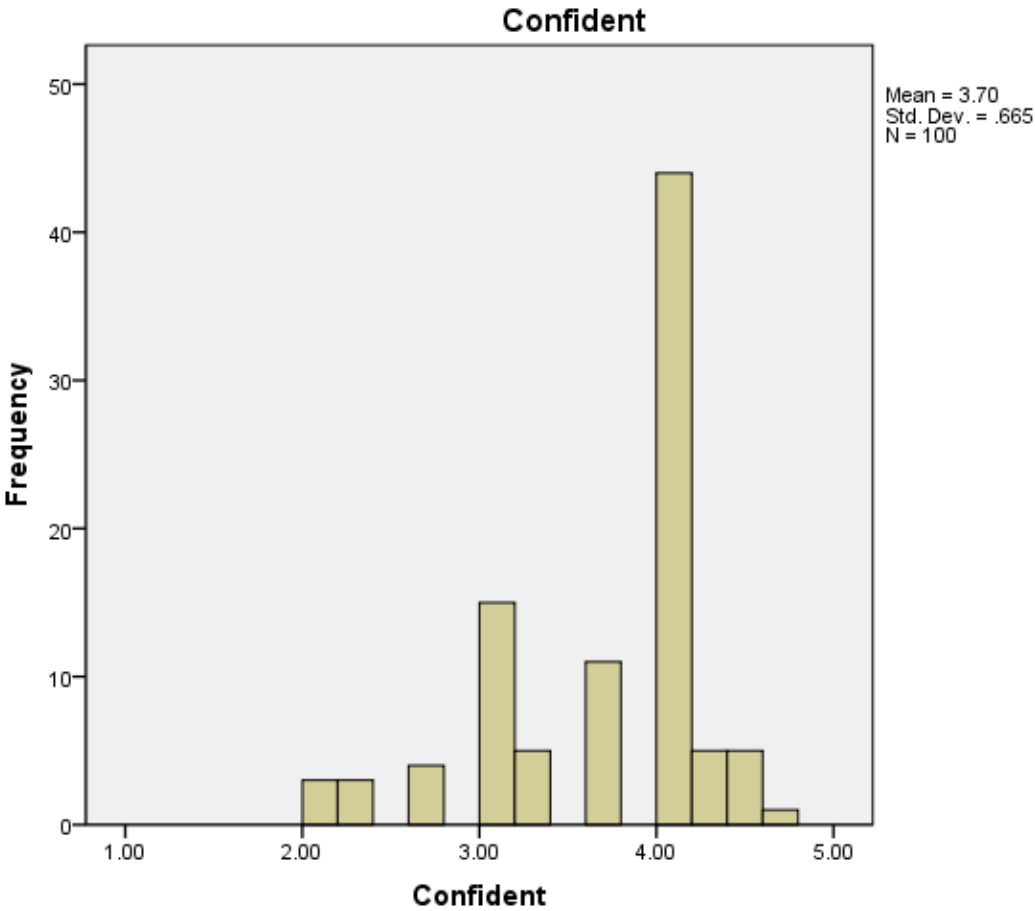


Figure 59. Distribution of confidence rating scores

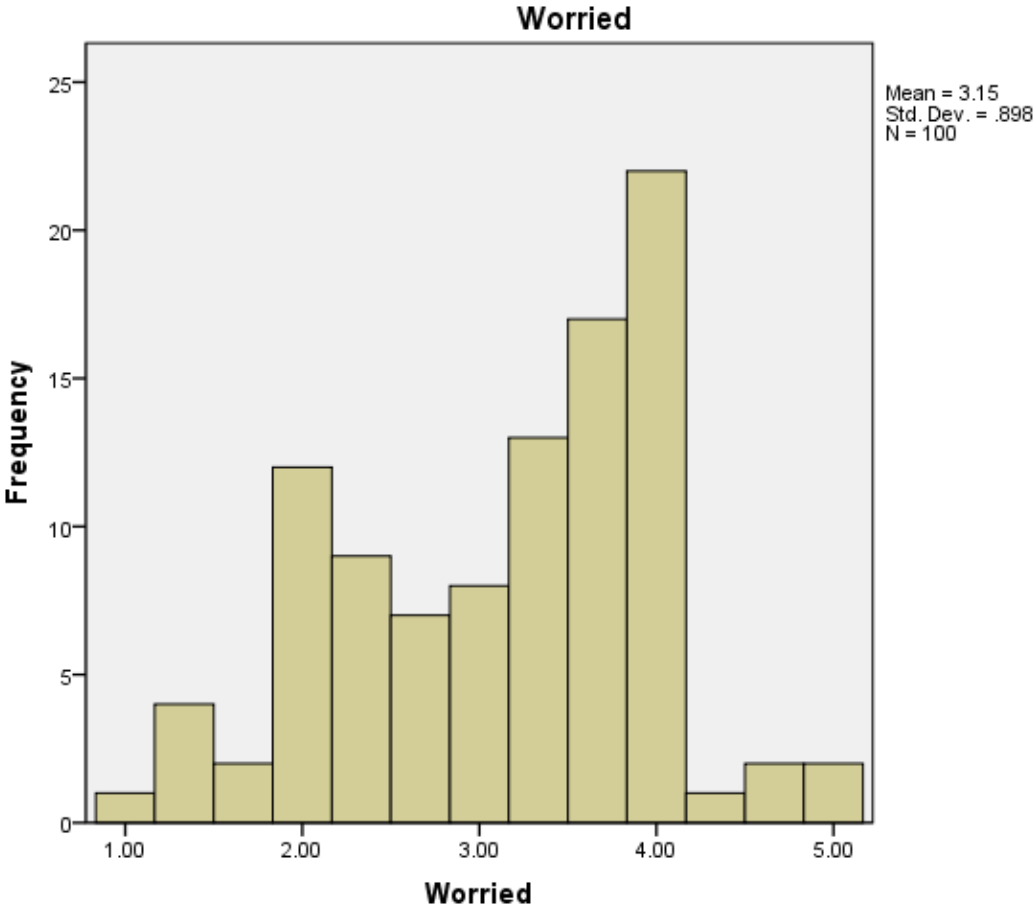


Figure 60. Distribution of worried rating scores

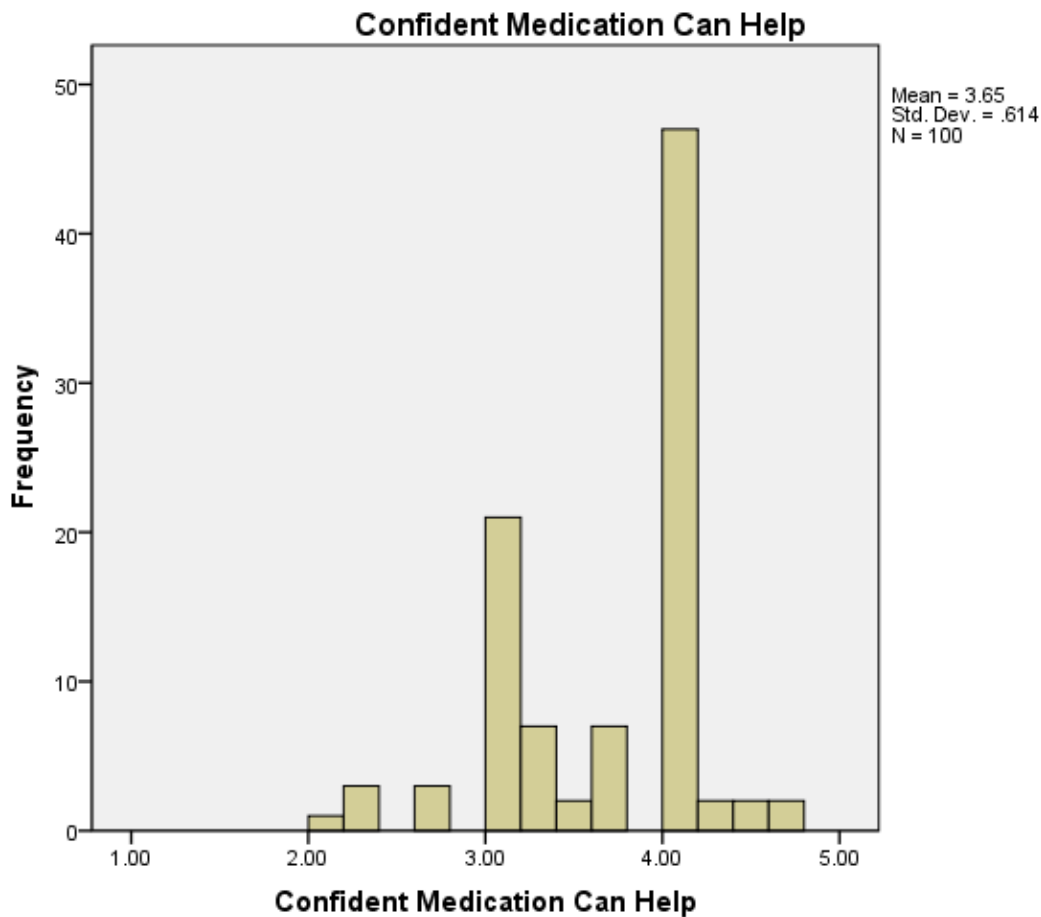


Figure 61. Distribution of confidence that medication can help rating scores

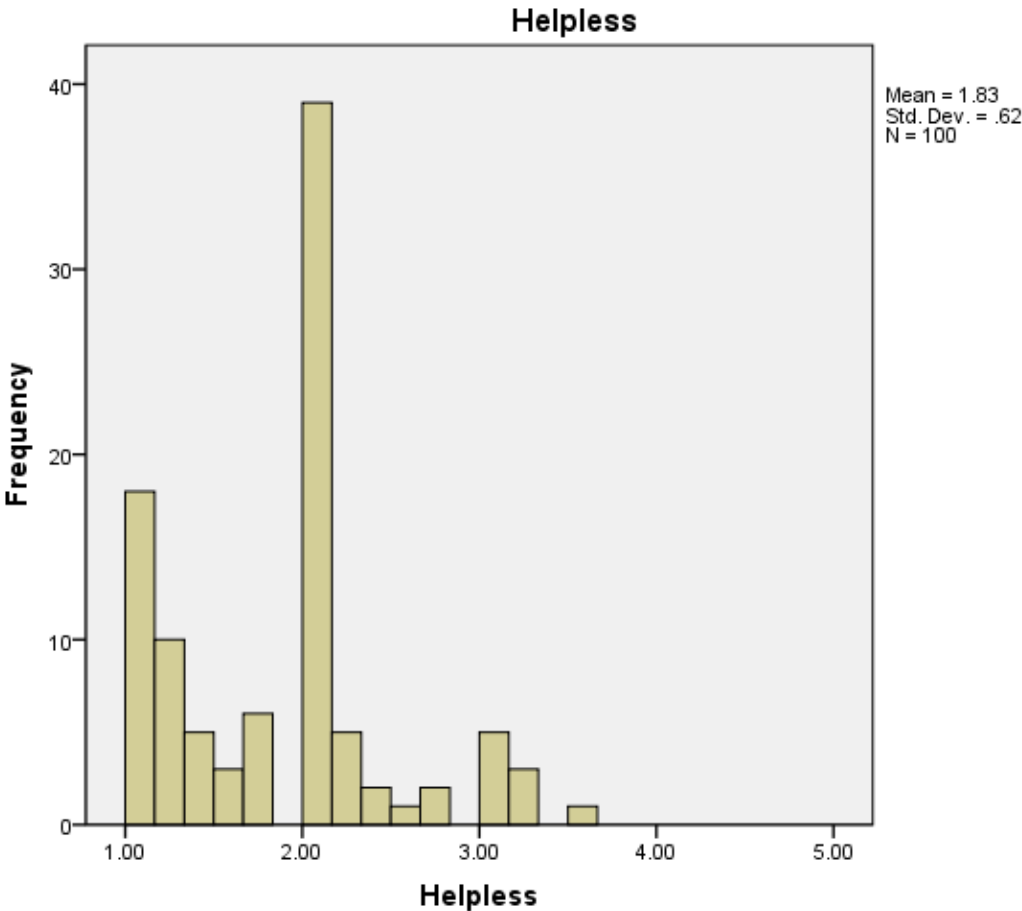


Figure 62. Distribution of helpless rating scores

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APPENDIX 24. First page of favourable opinion letter from research ethics committee for Study 5


Health Research Authority
NRES Committee London - Central
Skipton House
80 London Road
London
SE1 6LH
Telephone: 020 7972 2552

29 October 2012

Miss Sarah Jane Besser
PhD Student
King's College London
Department of Management, King's College London
1st Floor, Room 1.55
Franklin-Wilkins Building, 150 Stamford Street, London
SE1 9NH

Dear Miss Besser

Study title:	Evaluation of a psycho-educational, motivational interviewing and problem-solving intervention for adherence to osteoporosis treatment: a case series approach
REC reference:	12/LO/1648
Protocol number:	N/A

The Research Ethics Committee reviewed the above application at the meeting held on 24 October 2012. Thank you for attending to discuss the study.

Ethical opinion

- The Committee found no major ethical issues
- Members wondered whether the current follow up is not adequate, and will ask why there is no follow up after six months.
- Members would like further information regarding a previous study that participants were involved in, and if consent was given to future studies.

Miss Sarah Jane Besser and Dr Janet Anderson joined the meeting.
Discussion took place as follows:

- a. The Chair asked if she would be the first point of contact and had she already gained consent from a previous study, and asked if it might be more appropriate to write first instead of calling. You informed the Committee that you had already gained consent in a previous study and due to time restraints, telephoning is quicker than writing to participants, in addition to this you had already built up some rapport with the participants previously.
- b. The Chair asked if you could do a further follow up at the end of the study. Dr Anderson explained that your studies finish in September so time will not allow further follow up. You left copies of the Osteoporosis Personalised Information Booklet that you intend to send to participants at the end of the study.

APPENDIX 25. Participant drawings of bone pre- and post- intervention (Study 5)

Table 49. Participant 1. Bone drawings

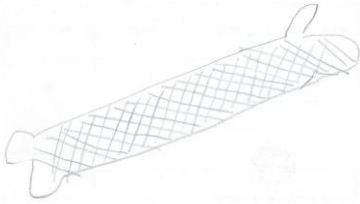
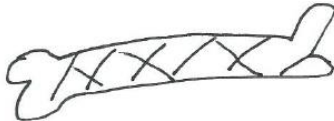
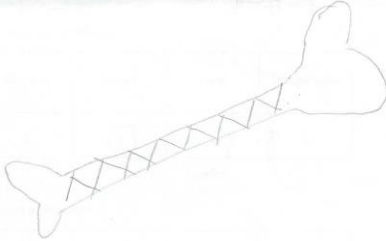
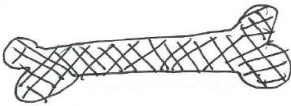
	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

Table 50. Participant 1. People drawings

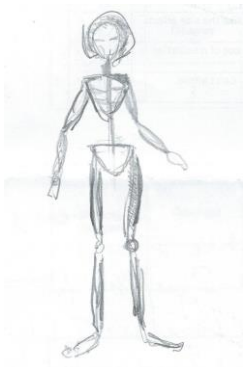

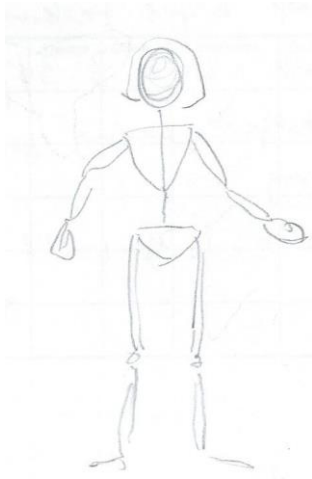

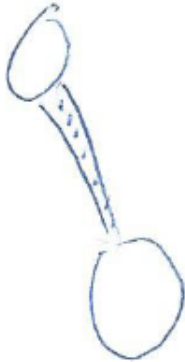


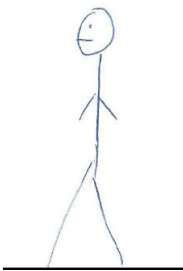
	Pre-intervention	Post-intervention
With osteoporosis	 A pencil drawing of a person standing, facing forward. The person has a very thin, fragile appearance, with a noticeably curved spine and thin limbs, suggesting osteoporosis.	 A simple stick figure drawing of a person standing, facing forward. The figure is thin and has a slightly hunched posture, suggesting osteoporosis.
Without osteoporosis	 A pencil drawing of a person standing, facing forward. The person has a more robust, healthy appearance, with a straight spine and thicker limbs, suggesting no osteoporosis.	 A simple stick figure drawing of a person standing, facing forward. The figure is thin but has a more upright posture than the one in the 'With osteoporosis' row, suggesting no osteoporosis.

Table 51. Participant 2. Bone drawings¹⁷

	Pre-intervention	Post-intervention
With osteoporosis	X	
Without osteoporosis	X	

¹⁷ Participant 2 reported that she did not know what to draw at baseline.

Table 52. Participant 2. People drawings¹⁸

	Pre-intervention	Post-intervention
With osteoporosis	X	
Without osteoporosis	X	

¹⁸ Participant 2 reported that she did not know what to draw at baseline.

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Table 53. Participant 4. Bone drawings








	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

Table 54. Participant 4. People drawings

	Pre-intervention	Post-intervention
With osteoporosis		<p>a) Front view</p>  <p>b) Side view</p> 

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Without osteoporosis		<div>a) Front view</div>  <div>b) Side view</div> 
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Table 55. Participant 5. Bone drawings

	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

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Table 56. Participant 5. People drawings





	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

Table 57. Participant 6. Bone drawings

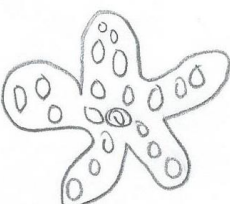
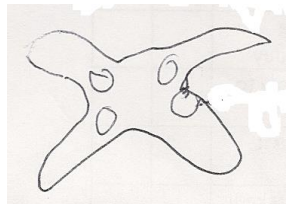
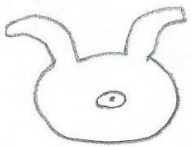
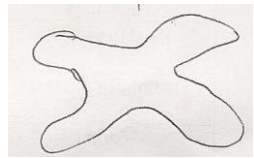
	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

Table 58. Participant 6. People drawings

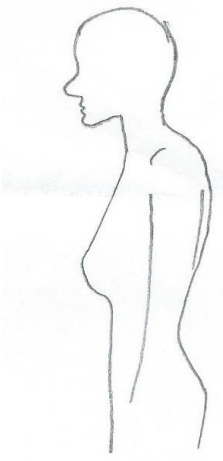

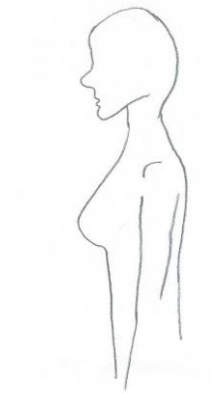
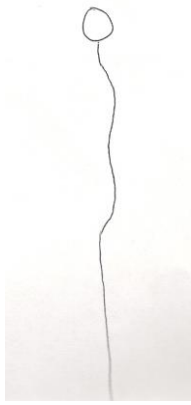
	Pre-intervention	Post-intervention
With osteoporosis		
Without osteoporosis		

Table 59. Participant 7. Bone drawings

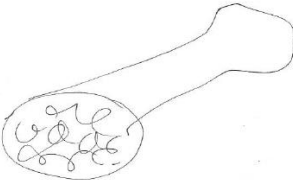
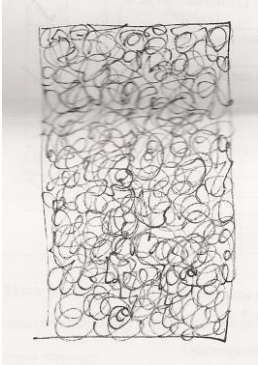
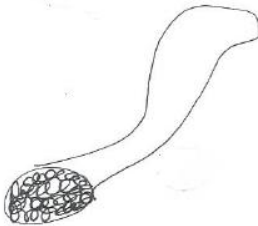
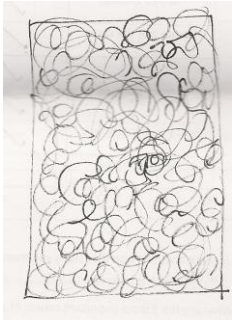




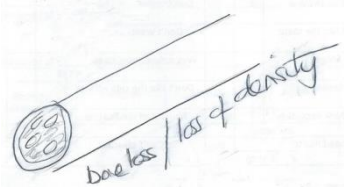
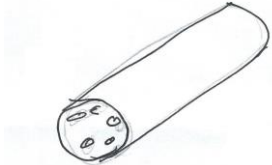
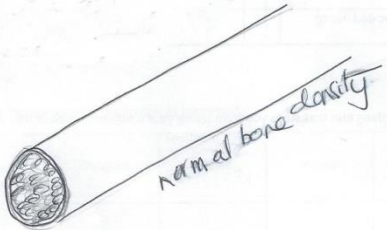
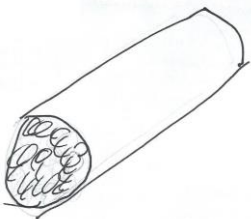
	Pre-intervention	Post-intervention
With osteoporosis	 A hand-drawn sketch of a long bone, possibly a femur, oriented horizontally. The proximal end (head) is on the left and is filled with a dense, scribbled pattern of overlapping loops and lines, representing porous or weakened bone structure. The shaft of the bone is relatively empty and tapers towards the distal end on the right.	 A hand-drawn sketch of a rectangular area filled with a very dense and intricate pattern of overlapping, swirling, and scribbled lines. The pattern is uniform across the entire rectangle, suggesting a highly porous or trabecular bone structure.
Without osteoporosis	 A hand-drawn sketch of a long bone, oriented horizontally. The proximal end (head) is on the left and is filled with a dense, scribbled pattern of overlapping loops and lines, representing porous or weakened bone structure. The shaft of the bone is relatively empty and tapers towards the distal end on the right.	 A hand-drawn sketch of a rectangular area filled with a very dense and intricate pattern of overlapping, swirling, and scribbled lines. The pattern is uniform across the entire rectangle, suggesting a highly porous or trabecular bone structure.

Table 60. Participant 7. People drawings

	Pre-intervention	Post-intervention
With osteoporosis	 A line drawing of a person from the side, leaning forward significantly with their back curved. They are holding a cane with their right hand for support.	 A line drawing of a person from the side, leaning forward less than in the pre-intervention drawing. They are holding a cane with their right hand.
Without osteoporosis	 A line drawing of a person from the front, standing upright with a straight back and arms at their sides.	 A line drawing of a person from the side, standing upright with a straight back and arms at their sides.

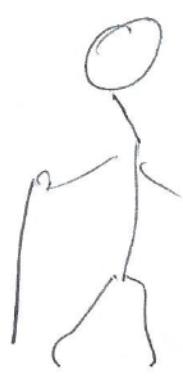
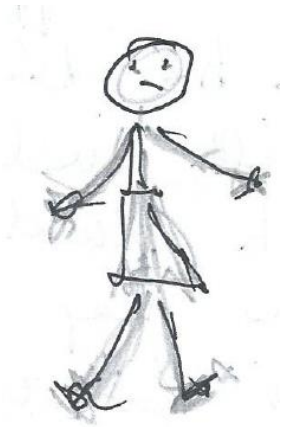



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Table 61. Participant 8. Bone drawings

	Pre-intervention	Post-intervention
With osteoporosis	 A hand-drawn diagram of a bone cross-section. The circular end of the bone is filled with several small, empty circles, representing a porous or less dense structure. A line points from the text "bone loss / loss of density" to this circular end.	 A hand-drawn diagram of a bone cross-section. The circular end of the bone is filled with a dense, stippled pattern, representing a more solid bone structure.
Without osteoporosis	 A hand-drawn diagram of a bone cross-section. The circular end of the bone is filled with a dense, stippled pattern, representing normal bone density. A line points from the text "normal bone density" to this circular end.	 A hand-drawn diagram of a bone cross-section. The circular end of the bone is filled with a dense, stippled pattern, representing a more solid bone structure.

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Table 62. Participant 8. People drawings

	Pre-intervention	Post-intervention
With osteoporosis		<p>Could look the same as without osteoporosis</p>  <p>Or</p> 
Without osteoporosis		

APPENDIX 26. Evaluation topic guide (Study 6)

Opening:

My aim here is to get a sense of your experience of being involved in the research for the last 4 months. The reason for doing this is that if the project was beneficial, it could be used with more people. If it was not beneficial, we would like to improve it.

Please note that this call is audio recorded and everything you say here is confidential. There are no right or wrong answers here, I am interested in your experience. If you would you would like me to rephrase any of the questions please ask.

This is about the work you did with Sarah, which we will call the research.

1. Evaluation of process

What did you think of THE RESEARCH? (*Acceptability*)

What was your interpretation of the purpose of THE RESEARCH? (*Coherence*)

Why did you agree to take part? (*Cognitive participation*)

Was it clear what you were required to do throughout THE RESEARCH? (*Coherence*)

2. Evaluation of thoughts and behaviour

Do you think you have changed as a result of THE RESEARCH? (*Effectiveness*)

Did THE RESEARCH change how you think about your osteoporosis? (*Effectiveness*)

Did THE RESEARCH change how you take your osteoporosis medication in any way?
(*Effectiveness*)

Did THE RESEARCH change your decision about how or whether you take medication in any way? (*Effectiveness*)

Did THE RESEARCH change how you think about osteoporosis medication?
(*Effectiveness*)

Which element of THE RESEARCH do you think helped you to change? (*Mechanism of effectiveness*) **only for patients who report that they have changed.**

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Apart from your medication-taking, did anything else change in your opinion?
(*Effectiveness*)

How important is to you to take your osteoporosis medication on a scale of 0-10?

With 0 being the least important and 10 being the most important.

(*Effectiveness*)

3. Evaluation of specific intervention components

You were posted an educational booklet. What did you think of the personalised information booklet you were sent? (*individual components*)

You received a telephone call from Sarah to check if you had any questions about the information in the educational booklet. She said she could refer any questions she could not answer to Dr FitzClarence. How did you find that?

What did you think of the hospital session you had with Sarah at UCH? (*Individual components*)

During the hospital appointment, you completed a worksheet with Sarah about the pros and cons of taking Strontium Ranelate. What did you think of that worksheet?
(*Individual components*) **only for some patients**

During your hospital appointment with Sarah, there was some discussion of your telephone questionnaire responses. What did you think of that discussion? (*individual components*)

During the hospital appointment, you and Sarah together made a plan for helping you to take your medication. How did you find the plan for helping you to take your medication? (*Individual components*)

Other than this research, has anything else happened to you over the last 4 months which might have changed your medication-taking? (*other factors*) **only for some patients.**

4. Evaluation of Acceptability

What did you like about THE RESEARCH? (*Acceptability*)

(prompts: education leaflet, hospital session, plan-setting, telephone follow-up)

What did you dislike about THE RESEARCH? (*Acceptability*)

(prompts: education leaflet, hospital session, plan-setting, telephone follow-up)

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Please rate on a scale of 1-5 how satisfied you were with THE RESEARCH (1 being the least satisfied and 5 being the most satisfied. Could you tell me why you gave it that score?

What could be done to improve THE RESEARCH for future use, to inform patients about their condition and help them with medication-taking?

Do you think the THE RESEARCH will continue to be of benefit to you now that it is complete? (*Maintenance*)

Would you recommend THE RESEARCH to a friend? Yes/No. Why?

Is there anything else you would like to say about the project?

Closing:

Thank you very much for this interview and for taking part in the study. Sarah will be sending you an M & S voucher to thank you for your involvement. A copy of the study results will also be sent to you when it is complete.

Please thank the patients for the large amount of time they have devoted to the study.

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

APPENDIX 27. Example of framework analysis of interview data for the theme ‘pre-intervention adherence and beliefs’ (study 6)

Participant	Sub-Themes					
	Pre-intervention Adherence	Pre-intervention barriers to Adherence	Pre-intervention Knowledge & Understanding	Pre-intervention perception	Pre-intervention side-effects	Pre-intervention experience of health care service.
1		<p>what was really difficult is that sometimes I'm going to bed and I'm watching television late at night then I think; oh I'll have a tangerine or something then I think Oh shit! It means I've got to get up at three o'clock in the morning and take the medication so you probably need to set your alarm! (4, 182 – 185)</p>	<p>I suppose with osteoporosis at the beginning you think osteoporosis; that's an old women's disease, but it isn't, that's the other thing I've learnt it isn't...</p> <p>PW: So it affects people of all ages really... (3, 140 – 145)</p>	<p>I think I was probably in a bit of a denial state at the beginning and it just made me open my eyes a bit really and I didn't even know, it just informed me a lot really. (1, 29 – 31)</p> <p>that's what made me go into a complete... No I'm not old, I haven't got this, this is ridiculous, I'm not taking the medicine... which made me not take it at the beginning, it's the way that its general perceived, I am of average intelligence so t hats how I perceived it before I went into the research or even thinking that I might have it all... (5, 239 – 242)</p>	<p>I had first of all been given tablets to take one a week which made me feel really sick...(2, 95 – 96)</p>	
2		<p>there was a time that I was on tetracycline and I discovered that I shouldn't be on both of them and in that case there was a couple of months a couple of years ago or last year that that I didn't take it but I think I might have mentioned that to Sarah as well, it was really because they asked me to be on tetracycline for a few months.</p> <p>(2, 86 – 89)</p>	<p>it's just that the medication that I'm on I had sort of doubts about whether they might cause other problems taking it, you end up with strong bones and everything else collapses around you! (laughs) (1, 18 – 20)</p>			
3	<p>Yes I was much more haphazard about it before (3, 120)</p> <p>I'm likely to have been a bit more easy going if I wasn't the study, the previous time I was on the strontium I was less committed to taking it really, I was forgetting more often...</p>		<p>I've been given to understand that strontium re-builds bones. I researched that and found out that that was the case. (1, 12 – 13)</p>			

The psychological factors in adherence to osteoporosis medication: an exploration and intervention development

Sub-Themes						
Participant	Pre-intervention Adherence	Pre-intervention barriers to Adherence	Pre-intervention Knowledge & Understanding	Pre-intervention perception	Pre-intervention side-effects	Pre-intervention experience of health care service.
	(3, 134 – 135)					
4				it's quite interesting because lots of people get strange conditions for instance somebody told me what it was like age 31 getting diabetes and suddenly finding that your body is letting you down, eating itself and not doing what it is supposed to do... I suppose that is what's happening with the aging process as well anyway... but psychologically it's a blow when what you thought was reliable is no longer reliable (4, 154 – 158)		
5	I'd stopped taking it and I wouldn't take it again even with all that I've been reading, I would you know, I'm sure other things would come out eventually, but I wouldn't take it again. (2, 72 – 74)		<p>I do see when I go up the clinics some people who are very bent over which is very sad you know, but I did know that you should have a lot of calcium (3, 142 – 144)</p> <p>I do do exercise and when I first started doing exercise, I don't know when that as... in the 1990's, you know when I first done my first study that's when I started to do exercise and that helps apparently. (3, 144 – 146)</p> <p>Yea I did know a lot about osteoporosis because doing the study before more or less on the border line you know because that was a big study then but it wasn't with strontium ranelate because that wasn't out, it was that one that you take once a week which was fine and you can't lay down with it, I think you can now (5, 230 – 233)</p>	I suppose I didn't really have Osteoporosis then but I had broken an arm but I was very near to getting it but I did get it in the end! (laughs). (2, 58 – 59)		

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6	I took it because I'd been told to take it but if I missed one or two I didn't really think about it too much (2, 53 – 54)		<p>I should have done a lot more online research about my condition which I didn't, I was given a lot of information a lot of information was said a lot of information by a friend who had done a lot of research and so I was quite ignorant about the illness (1, 44 – 47)</p> <p>I knew a reasonable amount but I also didn't know a lot about the medication I was given or why or how to interpret any of the bone scan results (1, 47 – 48)</p> <p>Yea I didn't feel that I knew really what this medicine was going to do for me I didn't know how valuable it was (2, 52 – 53)</p>			<p>it's quite a complicated area to talk about but basically you are given your medication in a very rushed environment and given your diagnosis in a very rushed environment and when I asked some questions of my consultant I don't feel as though I was treated very receptively, I don't want to criticise the consultant but that was my perception of it she was obviously in a rush, I felt a bit like I was being treated a bit like a bit of an idiot child really and it did make me a quite cross because you know I've got a degree I've had a whole career I'm at the end of my career I'm a reasonably intelligent person (1, 36 – 42)</p> <p>I mean I was given Calcium and Adcal I think for the first part of my diagnosis you know years ago and then when I was given a sheet to say sort of we are not giving out Calcium tablets anymore and this is the research paper to say why and I looked at the bottom and it was 2 years old, you know it was not very good. (7, 322 – 325)</p>
7		<p>before I had all these concerns and on top of that I, it was like this is what you're supposed to do; take it, so I was resisting that, so I had a level of resistance (1, 45 – 47)</p> <p>So before the research, I was really concerned about taking the medicine. (2, 59)</p> <p>I was depressed, it was making me depressed, I was allowing myself to be depressed because of this, it seemed like this was just another thing I had to do just because I had to</p>				

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		do it and it occurred to me that it wasn't doing me any good! (2, 63 – 65)				
8		<p>I said that the problem from my point of view and apparently I'm not alone, is this 4 hour fast, I don't have problems taking medication in any other way I mean I'm not somebody who is avert to medication or finds I can't swallow tablets or anything it's just that the 2 hours and then the medication then another 2 hours with my particular life style is really really difficult. (1, 23 – 26)</p> <p>if you sort of go out and about and go to the theatre or you eat afterwards or you just have late suppers which is what we tend to do if one is working late or whatever, then it means it is just quite hard and therefore I wasn't in anyway able to get that organised in the evening (1, 29 – 32)</p>				